Supreme Court, U.S.
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86-513

No.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1986

ORTHO PHARMACEUTICAL CORPORATION,

Petitioner,

—v.—

KATIE LAUREL WELLS (infant), BY HER MOTHER AND NEXT FRIEND, MARY MAIHAFER, AND FATHER, GARY S. WELLS,

and

MARY MAIHAFER (Individually),

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

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QUESTIONS PRESENTED

1. Whether the Eleventh Circuit improperly applied the clearly erroneous standard of review, and created a new standard for "scientific" cases, in affirming a judgment based on subjective expert opinions contradicted by the objective, scientific evidence?

2. Should this Court resolve the conflict with the other circuits created by misapplication of this standard by the Eleventh Circuit as well as the District of Columbia Circuit (*Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 105 S. Ct. 545 (1984)) which permits a federal appeals court in effect to avoid reviewing complex questions of scientific causation by taking any expert's testimony at face value?

3. Whether this Court should articulate a standard of review to be applied in cases hinging on complex scientific testimony so as to settle an important question of federal law and safeguard the integrity of the factfinding process?

LIST OF PARTIES TO APPEAL TO THE ELEVENTH CIRCUIT COURT OF APPEALS

The names of all the parties to the Appeal to the Eleventh Circuit Court of Appeals are provided in the caption to this Petition. Sup. Ct. R. 21.1(b). Ortho Pharmaceutical Corporation is a wholly owned subsidiary of Johnson & Johnson. Pursuant to Rule 28.1, the following are all of the affiliates of Johnson & Johnson, other than wholly owned subsidiaries:

American Biomaterials Corp.
Cambridge BioScience, Inc.
ens Biologicals, Inc.
Enzo Biochem, Inc.
Immunomedics, Inc.
Thoratec Laboratories Corp.

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OPINIONS BELOW

The orders of the Court of Appeals in this matter dated June 27, 1986 denying the cross-petitions for rehearing of the parties are annexed hereto at pp. A-203-08 of Appendix A. The opinion of the Court of Appeals dated May 6, 1986 affirming in part and modifying in part the judgment of the district court is reported at 788 F.2d 741, and annexed hereto beginning at p. A-1 of Appendix A. The opinion of the district court is reported at 615 F. Supp. 262, and annexed hereto at p. A-29 of Appendix A.

JURISDICTION

This Court has jurisdiction to review the opinion of the Court of Appeals under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Rule 52(a), Federal Rules of Civil Procedure:

> Rule 52. Findings by the Court
>
> (a) Effect. In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon, and judgment shall be entered pursuant to Rule 58; and in granting or refusing interlocutory injunctions the court shall similarly set forth the findings of fact and conclusions of law which constitute the grounds of its action. Requests for findings are not necessary for purposes of review. Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses. The findings of a master, to the extent that the court adopts them, shall be considered as the findings of the court. It will be sufficient if the findings of fact and conclusions of law are stated orally and recorded in open court following the close of the evidence or appear in an opinion or memorandum of decision filed by the court. Findings of fact and conclusions of law are unnecessary on decisions of motions under Rules 12 or 56 or any other motion except as provided in Rule 41(b).

STATEMENT OF THE CASE

With the exception of the plaintiffs' experts in this case, no scientist has ever publicly expressed the opinion that vaginal spermicides cause birth defects. Prominent researchers associated with the National Institutes of Health ("NIH"), the Centers for Disease Control ("CDC") and Harvard University, among others, have found no credible scientific evidence of an association between spermicides and birth defects. Likewise, two advisory panels of leading scientists appointed by the Federal Food and Drug Administration ("FDA") reached the same conclusion on all the available studies and decided that a warning of such risks is not warranted by the scientific evidence.

The plaintiffs' experts, relying on their idiosyncratic interpretations of four of the twenty-three scientific studies in evidence, opined otherwise. Both courts below recognized the inherently subjective nature of this opinion evidence but nevertheless found for plaintiffs. The trial court had to concede, however, that the evidence revealed only "a *possible* link between spermicides and birth defects." 615 F. Supp. at 292 (emphasis added), and indeed "found the studies to be *inconclusive* on the ultimate issue of whether the Product caused Katie Wells' birth defects." *Id.* (emphasis added; footnote omitted). Similarly, the Eleventh Circuit affirmed on the rationale that the product "might cause birth defects." *Wells*, 788 F.2d at 746.

Ortho respectfully submits that an objective review of these studies, as well as other publications relied upon by plaintiffs' experts, plainly reveals a complete lack of objective evidence proving causation. Complete copies of these materials have been lodged with the Court.

A. The Nature Of The Proceedings And The Disposition Below

Katie Wells was born in 1981 with a cleft lip, nostril deformity, deformity of her right hand, the complete lack of a left arm with only partial development of her left clavicle and shoulder, and hypoplasia of her right optic nerve. T 11.[1]

Her parents instituted this action against Ortho for, among other things, "the negligent failure to warn" that Ortho-Gynol might cause birth defects.

After a two-week trial, the district court (Judge Shoob) sitting without a jury found that plaintiffs had proven to a reasonable degree of medical certainty that Katie Wells' limb anomalies had been caused by the spermicide, but found otherwise with respect to her cleft lip and right optic nerve injury. T 1878-79. Judge Shoob also found that Ortho knew or should have known that its product might cause birth defects. T 1879; Re 185-86. Accordingly, he held Ortho liable to plaintiffs and awarded them damages in the total amount of $5.1 million, reduced on appeal to $4,736,030.

B. The Regulatory History Of Ortho-Gynol

Ortho-Gynol is a vaginal spermicide containing one active ingredient, "octoxynol," which is a non-ionic surfactant.[2] Ortho has been marketing this product since around 1950. T 1004-05; T 1007. The spermicide is sold as an over-the-counter ("OTC") drug for use with a diaphragm.

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1 Citations to "T ____" herein refer to the trial transcript; "Re ____ refers to record excerpts prepared by Ortho for the Court; and Aa ____ refers to the Appellant's Appendix below.

2 A surfactant is "a surface-active agent." The term "includes substances commonly referred to as wetting agents, surface tension depressants, detergents, dispersing agents [and] emulsifiers." *Stedman's Medical Dictionary* 1373 (24th ed. 1982). A non-ionic surfactant spermicide breaks down the sperm cell membrane. Once the outer membrane separates, the cell disperses its substance and ceases to function. T 177-78; *Population Reports*, "New Developments in Vaginal Contraception," 12(1):158 (Johns Hopkins Univ., Jan.-Feb. 1984) ("*Population Reports 1984*") (Aa 352, 356).

In the early 1970's, the Federal Food and Drug Administration ("FDA") established several expert advisory panels to review the "safety and efficacy" of all OTC drugs. *See* T 1057-58; 21 C.F.R. §§ 330.10 and 330.12; 37 Fed. Reg. 9,464, 9,466 (1972). The panel designated to review OTC contraceptives, including spermicides, first met on August 2, 1973. T 1061; 45 Fed. Reg. 82,014-15 (1980) (Aa 257). After a five-year investigation, including a worldwide literature search, active solicitation and consultation with numerous scientific and medical experts, T 1016; T 1062-71; 45 Fed. Reg. 82,015-16 (1980) (Aa 257-58); T 1012-14, this OTC panel submitted its final report to the FDA concerning OTC vaginal contraceptive drug products. *See* 45 Fed. Reg. 82,014-49 (1980) (Aa 255-91). The panel found, "without question," that vaginal contraceptives like Ortho-Gynol, which contain non-ionic surfactants, are "safe and effective for over-the-counter use." T 1083-84; 45 Fed. Reg. 82,014, 82,028-83,031 (1980) (Aa 270-73).

In November 1983, the FDA requested that one of its standing committees, the Fertility and Maternal Health Drugs Advisory Committee (the "FMHDAC"), evaluate "the safety of vaginal spermicides." T 1216-17; 48 Fed. Reg. 51,533 (1983). After considering the evidence, which included all of the available studies, the FMHDAC unanimously found that:

> [T]he preponderance of the weight of the currently available evidence indicates no association between the maternal spermicide exposure and an increased rate of abortions or congenital malformations.

Transcript of FMHDAC hearing (Aa 620-21).

C. Scientific Data Before The Trial Court

1) *Plaintiffs' Epidemiological Studies*

Thirteen epidemiological studies[3] were entered in evidence. None of the thirteen studies demonstrated an association between spermicide use and limb defects.[4] The trial court singled out two of these studies, Oechsli (Aa 6) and Smith (Aa 27), to support the finding that the product caused the birth defects involved here. Even these studies, however, demonstrate a critical lack of foundation for the findings of causation by the trial court.

Oechsli studied a group of women and utilized data gathered between 1959 and 1966, a time when some spermicides contained the mercury derivative, PMA, later withdrawn from the market because of an FDA finding of toxicity. Aa 9; T 179-80; T 670; T 757-58; T 890. This in and of itself prevents legitimate inferences from being drawn as to the spermicides presently in use. Oechsli reported no association between spermicide use and limb defects—the malformation involved here. The data yielded an association that was barely statistically significant between spermicide use and certain congenital heart defects among children of white women. The chances that this association was a fluke were heightened by the lack of any similar association among black women or among women as a whole.[5]

Inherent in the design of retrospective studies, such as those involved here, is the limitation that they can only show an

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3 Epidemiology is the medical science dealing with the relationships of the various factors which determine the frequencies and distribution of certain diseases and conditions in human populations.

4 Jicks (1981), the sole study that contained any data showing an association between spermicide use and birth defects, by its own terms lacked any real probative value. Jick himself noted that fundamental problems with his study "raises doubt" as to whether the association was real. Aa 36. The more glaring deficiencies are discussed *infra* at page 8.

5 The inability to infer causation from Oechsli's data is obvious, particularly in view of the fact that the data yielded a finding that black women who used spermicides had *lower* rates of birth defects. Aa 14.

association between two events and not a cause and effect relationship. There have been many examples of statistically significant associations which are undeniedly not cause and effect associations, such as Down's Syndrome and infectious hepatitis, or diabetes and inflamed gallbladders.[6] As pointed out in Mainland, *Elementary Medical Statistics*, pp. 117-22 (2d ed. 1964), a retrospective study can yield an association unrelated to cause and effect in one of two ways: 1) The person having the two events, here a woman using a spermicide and subsequently giving birth to a child with birth defects, or as in Berkson's study, a diabetic subsequently presenting with an inflamed gallbladder, is more apt to be carefully scrutinized for past medical history and thereby become part of a study sample; or 2) if the controls—*e.g.*, as here, women who have not given birth to babies with birth defects—are not representative of the same sample as that presented by the cases studied.

The race interaction, *i.e.*, an association among white women but not black, suggested to Oechsli that "the finding in the white group may have been a statistical fluke." Aa 16. On balance, he concluded that his data at most raised a "serious suspicion" requiring further research. Better designed and subsequent studies have never replicated Oechsli's data on heart abnormalities. Whether or not the statistical association was real or a fluke, however, the fact remains that Oechsli's data involved only an association between spermicides and heart abnormalities.[7]

The Smith study examined spermicides, among other agents, in an attempt to explain an increase in congenital limb deformities in Alberta, Canada between 1969 and 1971. Aa 27. This study likewise involved the same confounding spermicide,

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6 See Stoller *et al.*, *Incidence of Infective Hepatitis Followed by Down's Syndrome Nine Months Later*, Lancet 2:1221 (1965); Berkson, *Limitations of the Application of Fourfold Table Analysis to Hospital Data*, Biometrics Bulletin, 2:47 (1946).

7 As association is said to be statistically significant where the odds are 5% or less that the association found is due to chance.

PMA, as was involved in Oechsli. T 758; T 1300-01; T 1456. Smith concluded that "[n]o single causal relationship was established" (Aa 27) between any of the agents studied (including spermicides) and birth defects, and that his study was actually "reassuring" for continued use of spermicides. Aa 29.

Plaintiffs' experts disregarded Smith's own conclusion. Instead, they claimed that the study really found an association between spermicides and limb defects which emerged only after a large number of statistical manipulations performed by Smith, even though Smith himself recognized that such an association "might have been expected by chance." Aa 29; T 1300; Aa 57.

Eight epidemiological studies were published after August 1980. One of these, Jick (1981), was relied on by plaintiffs and the district court. Jick reported an association between spermicide use and limb reduction deformities, among other birth defects, but recognized problems with his study (among them inability to assure that the women studied had actually used spermicides for the relevant periods). He himself concluded that "the results should be considered tentative until confirmed by other data." Aa 47. Plaintiffs' primary expert, Dr. Buehler, agreed with that conclusion. T 357.

Jick's call for other data was quickly met. Within three years, four major epidemiological studies tested the validity of Jick's findings, using more precise exposure data. Subsequent to trial, two additional studies, one of which was introduced in draft form at trial, were published. Each of the studies highlighted the fact that, unlike the Jick study, exposure data (*i.e.*, whether a woman was using a spermicide at the time she became pregnant) were carefully ascertained. Each of them found no association between spermicide use and birth defects despite the fact that the CDC's study consisted of a sample "large enough to have virtually a 100 percent chance of detecting" such a relationship. Aa 64.

2) ***The Absorption Studies***

The only plausible mechanism of action postulated by plaintiff as to why spermicides might cause birth defects is that they may be absorbed through the vaginal wall and into a mother's circulatory system. T 243-44. There is, however, no objective evidence to support the theory that such absorption actually occurs. Four studies concerning absorption, two involving animals and two involving humans, were introduced into evidence. The human studies showed no such absorption. Nevertheless, the district court relied on the two animal studies and speculated that therefore such absorption occurred in humans as well as animals. This animal data, however, cannot substitute for proof of what happens in humans and even those animal studies do not establish teratogenesis in the animals.

Chvapil (1980) (Aa 98) concluded that slight amounts of non-ionic surfactants are absorbed through the vaginas of rats and rabbits, Aa 108-10, but as Buttar pointed out (1982) (Aa 112), the level of absorption was far below that considered to have teratogenic or any other pharmacological significance. Aa 116; T 1608; 47 Fed. Reg. 54,750, 54,751 (1982); T 1562-63.

3) ***The Animal Toxicity/Teratology Studies***

Seven other animal studies were introduced into evidence. Four of those studies examined whether spermicides evidenced systemic toxicity in animals. Three of them investigated the more specific issue of whether spermicides are teratogenic in animals.

Plaintiffs' causation experts and the district court purported to rely solely on a one-paragraph abstract of a single study involving rats by Buttar (1982) to support the hypothesis that spermicides penetrate through the vaginal wall. In the conclusion to his abstract, Buttar noted that the nonoxynol-9 "did not cause any discernible visceral or skeletal malformations" and that, therefore, a single dose of the substance is "embryolethal [*i.e.*, contraceptive] and fetocidal but *non-teratogenic in the rat at a dose approximately ten times higher than that*

recommended for controlling conception in women." Aa 156 (emphasis added).

However, just as with the Smith study, plaintiffs' experts chose to disregard the scientist's own conclusions based on data from his study. Instead, relying on the subsidiary finding that spermicides are embryolethal in rats at mega-doses, they conjectured this could also indicate they *might* be teratogenic. Even so, Dr. Buehler admitted that he did not "know what [Buttar's] embryolethality causation was." T 348.

D. Plaintiffs' Theories of Liability

Obviously the FDA sought to investigate far in advance of the trial in the District Court the "possibility" that spermicides "might cause" birth defects and to that end in 1983 requested its Standing Committee consisting of outstanding independent experts in the field of contraception and epidemiology to review this issue, including all of the studies before the District Court. 48 Fed. Reg. 51,534 (1983). This Committee concluded that there was no justification to warn actual or potential users of vaginal spermicides of a possibility of birth defects in event of a method failure and that no warning should accompany the product other than the statement "if vaginal irritation occurs and continues, contact your physician."

1) *Causation*

Dr. Buehler's subjective "belief" was that Katie Wells' limb defects had two distinct etiologies, T 298, and were caused by a vascular disruption attributable to spermicide. T 242-43; T 217; T 327. This hypothesis is pure speculation unsupported by any objective evidence.

Dr. Buehler claimed to rely on scientific literature to support two premises critical to his hypothesis: (1) that non-ionic surfactants are absorbed through the vagina into the mother's circulatory system and from there into the fetal circulatory system; and (2) his unconfirmed speculation that once in the fetal circulatory system, spermicides cause irritation and damage to the vascular supply, possibly by causing a blood clot which could result in a limb deficiency. T 243-44. In support of

the first premise, Dr. Buehler cited the animal absorption of Chvapil and Buttar. T 316-17. As discussed above, even if accepted at full face value, these studies do not support this theory. With respect to the second premise, namely that the pharmacologic properties of non-ionic surfactants irritate the blood supply or a blood vessel and cause clotting, Dr. Buehler himself conceded he knew of no objective scientific evidence supporting it. T 243.

Finally, Dr. Buehler relied "strongly" on the study by Buttar, which he asserted showed embryolethality in rats. T 268-69. He testified that he would have liked to see other animal studies using different genetic strains (T 335-36), and when shown such studies, had no credible explanation for their findings. These studies, which followed the FDA protocol, showed no teratogenicity or even embryolethality. *Id.*; T 391.

Dr. Buehler arrived at his opinion on causation to "a reasonable degree of medical certainty" by purporting to use the doctrine in medicine known as the diagnosis of exclusion. This doctrine allows a scientist to conclude that a particular agent is the cause of a condition by ruling out all other possible causative factors except the one under consideration. As a matter of basic science and mathematics, however, this doctrine—the diagnosis of exclusion—is inapplicable here. Dr. Buehler himself admitted that the etiology of 60% to 65% of birth defects is unknown. T 405-06. Thus, the failure to identify other possible external agents besides Ortho-Gynol is not sufficient to pinpoint it as the culprit. Moreover, despite his purported reliance on "absence of other causation," he conceded he could not "rule out" amniotic banding as a cause of the hand deformity. T 232.

Ortho's experts, an epidemiologist, Dr. Stolley, and an embryologist, Dr. Brent, pointed out the obvious fact that the existing medical literature simply provides no indication, let alone proof, that vaginal spermicides cause limb defects.

The embryologist expressed the opinion that Katie Wells' malformations were most likely the product of amniotic banding. As noted, the trial court found that scientific literature on

the claimed association between spermicides and birth defects was, at best, "inconclusive." Re 180. Because of the certainty with which Dr. Brent expressed his opinion, as well as the "bias" which the trial court believed both he and Dr. Stolley had exhibited, however, the trial court ruled that their opinions could not be credited. Re 162, 176-77. On the other hand, because the trial court found all of plaintiffs' experts save one to be "credible," and because the studies did not "rule out all possibility" that spermicides "might" cause birth defects, he found for plaintiffs. Re 107, 180.

2) ***Failure to Warn***

As noted, the trial court found that vaginal spermicides "might" cause limb defects, and found plaintiffs' experts to be "credible." Because these "credible" experts gave their opinion to "a reasonable degree of medical certainty" that the vaginal spermicide caused the limb defects in this particular plaintiff, the trial court not only found that they were in fact caused by the spermicide but that Ortho was negligent for failure to warn in its labeling of this possibility as soon as there was a " 'hint' of a possibility."

To summarize, the trial court ruled in favor of the side whose experts he liked on this complicated scientific issue and the appeals court held that because this was a "classic battle of experts," the trial court was entitled to use this subjective selection process as a rationale for reaching this result. If trials are in fact supposed to be a search for the truth, this irrational decision-making process and the ensuing appellate review process simply cannot stand.[8] It goes without saying that makers of mass produced products cannot be expected to continue marketing those products in the face of such irrational and expensive condemnations by the judiciary.

8 This precise issue was addressed by the "Tort Policy Working Group," a committee formed by the United States Attorney General in 1985, which found that the lower courts have abrogated their responsibility in complex "scientific" tort cases. The committee recognized that there is a pervasive problem in these cases of improper causation findings based on invalid medical and scientific testimony. *See*, "Report of the Tort Policy Working Group on the Causes, Extent and

(*cont'd on next page*)

THE REASONS FOR GRANTING THE WRIT

I. THE ELEVENTH CIRCUIT'S STANDARD OF APPELLATE REVIEW IS INADEQUATE TO INSURE THE INTEGRITY OF THE FACT-FINDING PROCESS IN CASES WHERE LIABILITY HINGES ON COMPLEX SCIENTIFIC TESTIMONY

This case presents an issue of critical importance: clarification of the proper standard of appellate review in cases based upon complex scientific data and conflicting scientific expert testimony. The Eleventh Circuit enunciated a new standard of review, purportedly based on *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 105 S. Ct. 545 (1984). This standard not only conflicts with other circuits' standards, but also contravenes the standard articulated by this Court in *Anderson v. City of Bessemer City*, 470 U.S. 564, 105 S. Ct. 1504 (1985). The panel's new standard for "scientific" cases improperly insulates the district court's findings from effective appellate review and dramatically increases the probability of unjust results in cases where the truth requires reliance on technical and scientific evidence capable of objective evaluation. The decision of the Eleventh Circuit in *Wells* highlights the crucial need for this Court to clarify the proper standard of appellate review for the ever-increasing number of cases which must be determined by evaluation of complex scientific or technical data.

A. The Eleventh Circuit's Decision Creates a New and Impermissible Standard of Appellate Review For "Scientific" Cases

This Court's standard of review in *Anderson v. City of Bessemer City*, was misapprehended and misapplied in this case by the Eleventh Circuit. The appellate court is required under Fed. R. Civ. P. 52(a) to determine "[i]f the district court's

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Policy Implications of the Current Crisis in Insurance Availability and Affordability," February 1986; *see, infra*, pp. 22-24.

account of the evidence is plausible *in light of the record viewed in its entirety . . .*" *Anderson*, 105 S. Ct. at 1512 (emphasis added). However, in the *Wells* case, the Eleventh Circuit in effect established a new standard of review for scientific cases. It narrowed the scope of its review to the oral testimony of the plaintiffs' experts (including their interpretations of the "inconclusive" scientific studies they relied on), without evaluating the plausibility of that testimony in light of the scientific studies admitted into evidence.

The panel's failure to comply with *Anderson*'s command to review the record in its entirety is well evident throughout its opinion. For example, rather than independently reviewing or analyzing the four principal studies relied upon by plaintiffs and plaintiffs' experts, the Court merely listed the four epidemiological sources in a footnote,[9] and relied on *plaintiffs' expert's* characterization of their contents. *Wells*, 788 F.2d at 744 n.6. That hardly constitutes an evaluation (or even a basis for an evaluation) of the sufficiency of the evidence.

In addition, the panel did not evaluate the district court's account of the evidence in light of the unanimous conclusions of two FDA review panels and the many scientific studies in evidence (including those by researchers with the NIH, CDC and Harvard University) finding no credible scientific evidence of any association between this type of spermicide and birth defects. Nor did the panel explain how Dr. Buehler's opinions could be "highly credible" despite his conceded failure to read a majority of the relevant scientific studies, much less account for their findings. T 366; T 379; T 389; T 397; T 399-402; T 391-92; T 394. *Compare Brown v. Syntex Laboratories, Inc.*, 755 F.2d 668, 673 (8th Cir. 1985); *Wisconsin v. Weinberger*, 745 F.2d 412, 422 (7th Cir. 1984). Indeed, the panel went beyond plaintiffs' experts' testimony when it found that: "Plaintiffs noted various studies relative to absorption suggesting that absorption of the spermicide by the mother produced vascular disruption in the fetus that led to the birth defects." *Wells*, 788 F.2d at 744-45 (footnote omitted). This is incorrect. It is

9 As noted above, Buttar's rat study is not an epidemiological work.

undisputed that only one of the plaintiffs' experts even testified that it was "possible" that spermicide could produce such a vascular disruption. T 543. Referring to it as "my opinion," Dr. Sutherland specifically stated that he knew of no study to support his view and had never "actually seen this specific written idea." T 554; T 627.

In proceeding to review the district court's findings of facts by focusing exclusively on the oral testimony of the plaintiffs' experts, and blindly accepting such testimony at face value, the panel disregarded this Court's admonition that a trial judge may not

> insulate his findings from review by denominating them credibility determinations, for factors other than demeanor and inflection go into the decision whether or not to believe a witness. Documents or objective evidence may contradict the witness' story; or the story itself may be so internally inconsistent or implausible on its face that a reasonable factfinder would not credit it. [*Anderson*, 105 S. Ct. at 1512-13].

Rather than comply with the broad-based review mandated by *Anderson*, the panel evidently determined that a different standard should be applied since this case involves complex scientific data and evaluation. The panel's decision to forego a fair and adequate review of all of the evidence and to accept blindly the plaintiffs' experts' oral evidence at face value was based on dicta from *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 105 S. Ct. 545 (1984). In *Ferebee*, the D.C. Circuit indicated that in any "battle of the experts" involving "complex and refractory causal issues . . . which stand at the frontier" of science, an appellate court should invariably sustain the trier of fact's choice of "the victor." The Court reasoned that:

> Judges, both trial and appellate, have no special competence to resolve the complex and refractory causal issues raised by the attempt to link low level exposure to toxic chemicals with human disease. On questions such as

> these, which stand at the frontier of current medical and epidemiological inquiry, *if experts are willing to testify* that such a link exists, it is for the jury to decide whether to credit such testimony. [*Id.* at 1534; emphasis added].

The panel interprets *Ferebee* to hold that in complex scientific cases appellate review is properly limited to the relatively mechanical task of ascertaining whether there is any expert testimony in the record which, if taken at face value, supports the trial court's decision.

The panel's decision to consider only the plaintiffs' experts' oral testimony, and its acceptance of their testimony at face value, led it to fail in its "unavoidable duty," *Dayton Board of Education v. Brinkman*, 443 U.S. 526, 534 n.8, *reh. denied*, 444 U.S. 887 (1979), to set aside factual determinations which, as here, are untenable in light of the record as a whole. Moreover, as discussed below, the panel's creation of this unique standard of review for cases involving complicated scientific data conflicts with the standard utilized by courts in other circuits as well as that mandated in *Anderson*.

B. The *Wells* Standard Improperly Insulates the District Court's Fact-Finding Methodology and Conflicts with Other Circuits and the *Anderson* Standard

In utilizing its new standard for review of cases involving complex scientific data, the panel failed to analyze the appropriateness of the district court's fact-finding methodology. Consistent with the mandate of *Anderson* and the practice of other Circuits, the panel had a duty to look behind the district court's finding of credibility of scientific testimony to determine whether "[d]ocuments or objective evidence may contradict the witness' story; or [whether] the [testimony] may be so internally inconsistent . . . that a reasonable factfinder would not credit it." *Anderson* 105 S. Ct. at 1512-13. A brief review of the testimony of only one of plaintiffs' experts highlights the type of flawed methodology utilized by the district court and impermissibly ignored by the panel.

For example, the panel noted Dr. Buehler's reliance on certain epidemiological studies, but failed to evaluate the appropriateness of this reliance, and thus never recognized that his analysis was literally meaningless. Dr. Buehler relied on several epidemiological studies, including (1) Oechsli (unpublished 1976) because it "indicated a question and possible relationship between spermicides and birth defects" (*Wells*, 788 F.2d at 744 n.6); (2) Smith (1977) because it "contained data suggesting an association between spermicides and limb deficiencies" (*id.*); and (3) Jick (1981) because it "raised a serious question about an association between spermicides and limb defects." *Id.*

The basic principles of epidemiology established in the record below, however, completely undermine Dr. Buehler's "analysis." An epidemiological study does not "suggest an association"; it either finds a statistical association or it does not. T 1357-58. Scientific data must, of course, be interpreted in accordance with scientific conventions. *Moultrie v. Martin*, 690 F.2d 1078, 1082 (4th Cir. 1982).[10] Dr. Buehler could not, therefore, produce any credible new insights or data with

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10 The Fourth Circuit in *Moultrie v. Martin* set forth the proper standard to be used in interpreting scientific or technical data in the courtroom. In a race discrimination case, for instance, when a litigant seeks to prove racial discrimination through the use of statistics, "he is borrowing the principles of another discipline, mathematics, and applying these principles to the law. *In borrowing from another discipline, a litigant cannot be selective in which principles are applied. He must employ a standard mathematical analysis. Any other requirement defies logic to the point of being unjust.*" *Moultrie*, 690 F.2d at 1082 (emphasis added); *accord* Loevinger, *Jurimetrics: Science in Law*, Scientists in the Legal System (W. Thomas ed. 1974) ("Scientists can best influence the adjudicatory process by working as scientists." "If scientists are to make a significant contribution . . . they must first produce relevant and significant scientific data and conclusions.").

As the Fourth Circuit indicated in *Moultrie*, the data utilized to create a prima facie claim of racial discrimination in a Title VII action must be statistically significant. Consequently, an expert could not, based on a disparity in the raw data that lacks statistical significance, nonetheless testify that those data "suggest" racial discrimination. Yet, that is precisely what Dr. Buehler did here.

respect to his reliance on the relevant epidemiology because he was not qualified to make an independent analysis of the scientific data contained in these epidemiological studies. Dr. Buehler himself conceded his professional incompetence in this area several times, explaining that "I'm not an epidemiologist. That's outside my expertise," T 352 and T 358, "I don't know how to figure [statistical significance]," T 353, and "I don't understand confidence levels. I never use them." T 358.

When all is said and done, the sole statistical or objective evidence on which the causation finding was based remains the race interaction statistical association found by Oechsli regarding heart abnormalities among children of white women as opposed to black women or women of both races combined. Statistical associations by definition cannot prove cause and effect relationships. Here, the sole association even found appears to be one of chance and not actually probative of the defect suffered. Accordingly, plaintiffs' experts themselves had to acknowledge the "well-known principle of epidemiology that for the results of a study to be considered valid they must be replicated." T 614; T 773-74; T 328-30. Moreover, plaintiffs' experts also had to concede that none of the studies they relied upon had ever been replicated, thereby precluding legitimate reliance on that association. *See*, *e.g.*, T 774. Thus, Dr. Buehler's analysis of the data, by his own terms, cannot be valid.[11]

In the final analysis, the panel's application of its new standard of review for scientific cases allowed it to sidestep these and other blatant methodological flaws that permeate the district court's factual findings. Relying on *Ferebee*, the panel reasoned that because "a cause-effect relationship need not be *clearly* established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship

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11 In a footnote, the panel acknowledged Ortho's argument on the undisputed scientific requirement of replication (*Wells*, 788 F.2d at 744 n.4), and then entirely ignored that critical principle in its review of the case.

exists," *Wells*, 788 F.2d at 745 (quoting *Ferebee*, 736 F.2d at 1535 [emphasis added]), a trier of fact may, therefore, reasonably find causation even if "the medical community might require more research and evidence before *conclusively* resolving the question." *Wells*, 788 F.2d at 745 (emphasis added). These truisms do not meet the issue in this case. Here the burden of proof is, or should be, the same as that used in the scientific community: does the objective evidence establish that a) it is more probable than not that this vaginal spermicide on occasion causes limb defects; and b) is it more probable than not that it did so here? This is undoubtedly why the law requires only that an opinion be expressed to a *reasonable* degree of medical certainty.

Thus, *Ferebee*'s purported distinction between "legal sufficiency" and "scientific certainty" (736 F.2d at 1536) is actually a mask for ignoring science. Science does not require certainty. Proof in law and proof in science dovetail. Both science and law seek to determine what *probably* occurred based on *all* of the reliable evidence. *See* Loevinger, *supra* at 22 (W. Thomas ed. 1974) ("Science is like law in that it is a mode of seeking agreement among different individuals with respect to certain [factual] questions. . . . The common elements in both have been an effort to be wholly rational, to organize and institutionalize the search for truthful data, and, above all, seek truthful data as the basis for judgments. Science can equally accept the basic principles of the legal system: to accept only rationally probative evidence and to examine all relevant evidence.").

Here the panel relied on *Ferebee*'s strawman distinction to rationalize legal liability where the scientific evidence is, at best, conjectural. As a factual matter, it is virtually impossible to prove that any substance taken by a pregnant woman does *not* cause birth defects, but where, as here, there is no plausible mechanism of action and no credible epidemiological data that the substance in issue does cause birth defects, that should end the inquiry.

The Eleventh Circuit sought to neutralize the lack of objective scientific evidence by explaining that the district court's "ultimate focus was *the birth defects suffered by Katie Wells*." *Wells*, 788 at 745 (quoting 615 F. Supp. at 292 [emphasis in the original]). Like the district court, the panel ignored a logical prerequisite in leaping to the "ultimate focus." Before it can be determined that a substance was the cause in fact of an individual's birth defects, it must be established as a general proposition that it can cause birth defects in the first place. The district court, however, found that the data relied on by the plaintiffs' experts on the question of causation in general only "indicated a possible link between spermicides and birth defects." *Wells*, 615 F. Supp. at 292. Therefore, it is logically impossible to find that this "possible" cause of birth defects was "more likely than not" the probable cause of the birth defects in this case.

In its reliance on *Ferebee*'s inherently untenable distinction between legal and scientific proof to justify the district court's failure to weigh in the balance anything but plaintiffs' experts' testimony, the panel ignored its duty to determine whether plaintiffs' experts utilized a "sound" methodology in reaching their conclusions. In thus aligning itself with the D.C. Circuit in *Ferebee*, the panel established a standard of review in "scientific" cases that directly conflicts with that of other circuits.[12] For example, in *Wisconsin v. Weinberger*, 745 F.2d

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12 Where, as here, a trier of fact has found an expert's data "inconclusive" and indicative of no more than a "possibility" of causation, as in this case, an expert's "demeanor" cannot serve as a surrogate for a finding of causation to a reasonable degree of medical certainty. If judicial proceedings are to be actual *fact* finding proceedings, scientific evidence cannot be ignored because of a fact-finder's preference or dislike of an expert's demeanor, tone and possible biases. As one court observed:

> [T]his Court was extremely impressed with the sincerity of Dr. Winsch, plaintiff's . . . expert witness. Dr. Winsch obviously thoroughly studied the various theories relating to the cause of MS and carefully explained to the Court the basis for his opinion. . . . *[A]s compelling as plaintiff's theory is, it remains an unproven theory only* and those physicians with more experience than Dr.

(*cont'd on next page*)

412, 422-24 (7th Cir. 1984), the Seventh Circuit reviewed the district court's fact-finding methodology, including an independent review of representative samples of highly technical, scientific evidence. On the basis of that review, the Court determined that the district court's finding in plaintiffs' favor was "clearly erroneous" because the scientific studies their experts had relied on were "generally unimpressive and cannot be deemed sufficiently significant." *Id.* at 424.

Similarly, in *Lima v. United States*, 708 F.2d 502, 506 (10th Cir. 1983), the Tenth Circuit conducted an independent review of the trial court's fact-finding methodology, including the data upon which experts relied. Upon that review, the Court upheld the trial court's finding that swine flu vaccine was a proximate cause or contributing factor of plaintiff's neurological disorder. In *Moultrie v. Martin*, 690 F.2d 1078 (4th Cir. 1982), the Fourth Circuit extensively reviewed and rejected the methodology used by the litigant where the litigant relied upon complex statistical and mathematical principles, and failed to apply these principles and data in a way consistent with the general principles of mathematics. *Id.* at 1082.

> Winsch in the relevant fields have not been able to conclude as he has, that the swine flu shot caused MS in any person. . . . There is, therefore, very little medical literature to support Dr. Winsch's opinion and the studies that are available cast some doubt on the viability of plaintiff's theory.

Hupp v. United States, 563 F. Supp. 25, 29 (S.D. Ohio 1982) (emphasis added); *See, also, New England Coalition on Nuclear Pollution v. NRC*, 582 F.2d 87, 100 (1st Cir. 1978) (An expert's credibility "is a function of logical analysis, credentials, data base, and other factors readily discernible to one who reads the record."); *Allan v. United States*, 588 F. Supp. 247, 416-43 (D. Utah 1984); *See, generally*, W. Gellhorn & C. Byse, *Administrative Law* 1056 (4th ed. 1960) ("Scientific questions . . . will not be decided upon the basis of the witnesses' behavior while testifying.").

C. This Case Presents an Urgent And Recurring Problem Which Threatens the Availability of Essential Goods to the Public

Today the legal system, if it is to fulfill its function in a complex society, must rely on objective evidence on scientific matters such as the safety and efficacy of drugs, *United States v. Rutherford*, 442 U.S. 544, 555 (1979), the dangers presented by chemicals in the workplace, *American Petroleum Inst. v. OSHA*, 581 F.2d 493 (5th Cir. 1978), *aff'd sub nom. Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607 (1980), and the safety requirements of nuclear power plants. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984). Both in the context of private litigation and in judicial review of administrative action, courts now deal with scientific issues of profound significance. *See* Tribe, *Legal Framework for the Assessment and Control of Technology*, 9 Minerva 243 (1973); *Katz, The Function of Tort Liability in Technology Assessment*, 38 Cin. L. Rev. 587 (1969).

Because erroneous decisions can have profound social consequences, in addition to their injustice, judges and legal scholars have continually sought to structure the courts' fact-finding methodology, *see, e.g., Symposium on Science and the Rules of Legal Procedure*, 101 F.R.D. 599 (1983). The fact-finding process must be structured to cope with "the anomaly of asking a lay judge or jury to resolve a dispute between experts on a subject about which they know nothing other than what the experts have told them." Bereano, *Courts as Institutions for Assessing Technology*, Scientists in the Legal System 88 (W. Thomas ed. 1974).

The judiciary's lack of a structured fact-finding methodology for "scientific" cases has critically undermined its ability to deal with complex medical and scientific concepts in a principled and rational manner. The ever-increasing "reliance of judges and juries on noncredible scientific or medical testimony, studies or opinions" has been thoroughly examined

by the "Tort Policy Working Group,"[13] in a report issued February 1986. "Report of the Tort Policy Working Group on the Causes, Extent and Policy Implications of the Current Crisis in Insurance Availability and Affordability," February 1986, ("the Report"), p. 35. The committee found that

> "[o]ne of the most pernicious developments in tort law has been the extent to which causation findings are based on fringe scientific or medical opinions well outside the mainstream of accepted scientific or medical beliefs. Increasingly, jurors are asked to make difficult decisions about highly complicated issues of science and medicine. *Unfortunately, the personality and demeanor of expert witnesses often may be more critical in making such determinations than decades of evolving scientific and medical investigation and thought.* [*Id.* at 62; emphasis added].

The Report further highlights the fact that, as in this case, the courts' use of scientifically and medically invalid evidence "has resulted in findings of causation which simply cannot be justified or understood from the standpoint of the current state of credible scientific and medical knowledge." *Id.* at 32. Moreover, the committee found that this dangerous development in tort law has produced a "deep and growing cynicism" for the judiciary's ability to properly resolve cases involving difficult scientific or technical concepts.[14] *Id.* at 35. The committee stated that

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13 The "Tort Policy Working Group" is a committee set up by the United States Attorney General in 1985 and composed of representatives from ten federal agencies and the White House. The primary representatives are from the Department of Justice, Department of Commerce and the Small Businesses Administration.

14 The committee made several recommendations for solving the problems created by the lack of an effective fact-finding methodology for complex scientific cases:

1) The courts should become "more aggressive in determining the credibility of scientific and medical evidence and opinions," *id.* at 35; and

(*cont'd on next page*)

> This problem has resulted in the growing perception that the tort system often is wholly arbitrary in allocating liability in cases involving difficult issues of science and medicine. This is a particularly problematic situation in toxic tort and drug liability cases. [*Id.* at 62]

The threat of the imposition of liability on a nonfactual basis, such as that relied upon in this case, is felt most acutely in the health and pharmaceutical field, where causation is necessarily complex and often uncertain, *see* Lewin, *Pharmaceutical Companies Are The Hardest Hit*, N.Y. Times, Mar. 10, 1985, § 3, at 1, while some risks are recognized to be unavoidable as a matter of law. See comments j and k to *Restatement (Second) of Torts*. For example, pharmaceutical manufacturers have ceased making DPT or whooping cough vaccines and IUD's as a direct result of the danger of excessive and unpredictable products liability verdicts. *See* Lewin, *supra*; *see also* Lewin, *Contraceptive Suits a Concern*, N.Y. Times, June 10, 1986, at D2 (suits for rare, unavoidable side effects of IUD prompted manufacturer to cease production; Planned Parenthood concerned that this reduces women's access to effective birth control; *Wells v. Ortho* and possible withdrawal of spermicide also cited with concern); Wash. Post, Dec. 20, 1984 § 1, at A18 (shortage of DPT vaccine occurs, since only one distributor of DPT vaccines remains because two others have ceased either production or distribution due to damages suits).

This Court should grant the petition for certiorari to address the issues concerning the interrelationship between science and law, and to clarify the appropriate standard of review in cases hinging on complex scientific data. The Eleventh Circuit's

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2) *Greater deference must be paid to government agencies* and certain private institutions *that have devoted decades of attention and millions of dollars to researching and trying to assess the value of medical and scientific developments.* Where such agencies and institutions have determined that particular products, services or techniques are safe or socially beneficial, courts should tread very carefully in overruling those judgments through the vehicle of tort law. *Id.* at 63 (emphasis added).

unique standard must be rejected by this Court. It serves to defeat the intrinsic purpose of appellate review because it greatly increases the probability that the result in a "scientific" case like *Wells* will not "reflect the truth and the right of the case," *Armstrong Cork Co. v. World Carpets, Inc.*, 597 F.2d 496 (5th Cir.), *cert. denied*, 444 U.S. 932 (1979).

CONCLUSION

For the reasons set forth above, the petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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86-513

No.

Supreme Court, U.S.
FILED
SEP 25 1986
JOSEPH F. SPANIOL, JR.
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1986

ORTHO PHARMACEUTICAL CORPORATION,

Petitioner,

—v.—

KATIE LAUREL WELLS (infant), BY HER MOTHER AND NEXT FRIEND, MARY MAIHAFER, AND FATHER, GARY S. WELLS,

and

MARY MAIHAFER (Individually),

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

APPENDIX

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KATIE LAUREL WELLS, ET AL.,

Plaintiffs-Appellees,

v.

ORTHO PHARMACEUTICAL CORPORATION,

Defendant-Appellant.

No. 85-8683

United States Court of Appeals,
Eleventh Circuit

May 6, 1986.

Appeal from the United States District Court for the Northern District of Georgia

Before GODBOLD, Chief Judge VANCE, Circuit Judge, and THOMAS*, Senior District Judge.

VANCE, Circuit Judge:

Defendant Ortho Pharmaceutical Corporation ("Ortho") appeals a $5.1 million judgment in favor of plaintiffs Katie

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* Honorable Daniel H. Thomas, Senior U.S. District Judge for the Southern District of Alabama, sitting by designation.

Laurel Wells, an infant, Mary Maihafer, her mother, and Gary Wells, her father, under theories of negligent failure to warn and strict liability. The case concerns a spermicide manufactured by Ortho that allegedly caused Katie Wells to be born with birth defects. After reviewing the extensive factual record we affirm with respect to Ortho's liability but modify the amount of damages.

I. Factual Background

Katie Laurel Wells was born on July 1, 1981 with birth defects including deformity of her right hand, the complete lack of a left arm with only partial development of her left clavicle and shoulder, a cleft lip, and nostril deformity. A later diagnosis showed that she also has an optic nerve defect in her right eye. The plaintiffs alleged that these birth defects were caused by a

spermicidal jelly used by the mother for approximately four weeks after conception until she discovered that she was pregnant.[1] The spermicidal jelly used by Mary Maihafer, in conjunction with a diaphragm, was manufactured and marketed without a prescription by Ortho. Called Ortho-Gynol Contraceptive Jelly ("Ortho-Gynol"), this vaginal spermicide has as its active ingredient a non-ionic surfactant known as Octoxynol-9.[2] The Ortho-Gynol label and package insert in 1980 contained only this warning -- the spermicide might cause irritation to the female or male genitalia, is not 100

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1 Mary Maihafer obtained the spermicidal jelly and a diaphragm from her physician in July 1980 and used them every time she engaged in sexual intercourse with Gary Wells until the middle of November 1980.

2 A non-ionic surfactant spermicide works by breaking down the sperm cell membrane.

percent effective, and should be kept out of the reach of children.

Plaintiffs brought suit against Ortho alleging that Ortho-Gynol caused Katie Wells' birth defects, that Ortho negligently failed to warn that its spermicide could cause serious birth defects, and that Ortho's failure to warn proximately caused the birth defects. Plaintiffs sought damages for Katie Wells' pain and suffering, medical expenses and disability, as well as Mary Maihafer's emotional distress and lost wages. The parties waived a jury, and the district court tried the case from January 1 through January 22, 1985. The district court found that plaintiffs had proven to a reasonable degree of medical certainty that the birth defects of Katie Wells' left arm and shoulder and her right hand were proximately caused by

Ortho's product, but found otherwise with respect to her cleft lip, nostril deformity and right optic nerve defect. The district court also found that Ortho knew or should have known that its product might cause birth defects. Damages were awarded exceeding $5.1 million.[3]

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3 The district court broke down the damage award as follows:

(1) Katie Wells:

(a)	loss of future earning	$ 415,000
(b)	future medical expenses	$1,200,000
(c)	past and future pain and suffering	$3,000,000

(2) Mary Maihafer:

(a)	medical expenses of Katie Wells	$ 30
(b)	loss of earnings	$ 36,000
(c)	mental distress	$ 500,000

Ortho later moved to reopen the trial for the consideration of two new scientific studies, but the district court denied this motion.

II. Discussion

In this appeal we must examine the district court's factual findings under the clearly erroneous standard. In our review we are guided by Anderson v. City of Bessemer City, -- U.S. -- , 105 S.Ct. 1504, 84 L.Ed.2d 518 (1985), in which the Supreme Court stated:

> "In applying the clearly erroneous standard to the findings of a district court sitting without a jury, appellate courts must constantly have in mind that their function is not to decide factual issues de novo." Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100,, 123, 89 S.Ct. 1562, 1576, 23 L.Ed.2d 129 (1969). If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it

> would have weighed the evidence differently. Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous.

Anderson, -- U.S. at -- , 105 S.Ct. at 1511-12.

A. Causation

[1] Defendant Ortho argues that plaintiffs failed to prove causation to a reasonable degree of medical certainty. See Robertson v. Emory University Hospital, 611 F.2d 604, 608 n. 13 (5th Cir. 1980); Parrott v. Chatham County Hospital Authority, 145 Ga.App. 113, 243 S.E.2d 269, 270 (1978). Ortho asserts that the district court made a clearly erroneous finding of fact concerning causation and that this finding derives from a clearly erroneous fact-finding methodology. Ortho complains that despite the inconclusive nature of the scientific and medical studies introduced, the district

court erroneously held that plaintiffs carried their burden of proof regarding causation. Ortho argues that the district court's findings based on the oral testimony of plaintiffs' experts should be set aside because those findings are not based on opinions with scientifically reliable foundations. In Ortho's estimation plaintiffs failed to focus sufficiently on epidemiology -- the field of science dealing with the relationships of the various factors which determine the frequencies and distributions of certain conditions and diseases in human populations.[4] Ortho asserts that epidemiological studies should be relied on to provide the essential data to formulate

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4 Ortho further argues that while plaintiffs' experts did rely on a few epidemiological studies that suggested a causal hypothesis, the inability of later studies negates the hypothesis.

an opinion on causation. Ortho also challenges the district court's credibility choices in analyzing both sides' experts.

[2] After reviewing the record we reject Ortho's arguments and conclude that the district court's finding of causation is not clearly erroneous. We note that plaintiffs presented well qualified experts who testified at length concerning causation.[5] These experts

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5 Plaintiffs' principal experts concerning causation were Dr. Bruce Buehler, Dr. Earl Sutherland, and Dr. John Holbrook. Dr. Buehler is the director of the Center for Human Genetics and director of the Meyer Children's Rehabilitation Institute in Omaha, Nebraska. Dr. Buehler's research area is biochemical teratology, the study of the effects of drugs or environmental agents on development fetuses. He is board-certified in clinical genetics, pediatrics, and biochemical and metabolic genetics. Dr. Sutherland is a licensed physician with a Ph.D.

(footnote continued on next page)

relied on their particular areas of expertise, their personal examinations of the child (at least by Dr. Buehler and Dr. Sutherland), and medical and scientific studies relative to causation to conclude that Ortho-Gynol caused Katie Wells' birth defects. Plaintiffs presented several epidemiological studies that indicated an association between spermicide use and deleterious effects

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(footnote continued from previous page)

in pharmacology. He is board-certified in internal medicine and has served since 1980 as the medical director of the Rocky Mountain Drug Consultation Center, which disseminates medical and pharmacological information to consumers and health professionals. Dr. Holbrook is the director of research and associate professor at Mercer University Southern School of Pharmacy in Atlanta, Georgia. He has a B.S. degree in pharmacy and a Ph.D. in pharmacology and has done extensive research on the toxic effects of drugs on various animal species.

on the fetus.[6] Plaintiffs noted various studies relative to absorption suggesting

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6 The epidemiological studies principally relied on by plaintiffs and plaintiffs' experts are as follows:

(1) Oechsli, Studies of the Consequences of Contraceptive Failure (Apr. 8, 1976) (unpublished study). According to Dr. Buehler, this study indicated a question and possible relationship between spermicides and birth defects. Frank W. Oechsli, Ph.D., of the School of Public Health at the University of California, Berkeley, produced the study for the Contraceptive Evaluation Branch, Center for Population Research, National Institute of Child Health and Development. A later published study by Harlap in 1980 cited the Oechsli study, though the Harlap article disagreed with it.

(2) Smith, Dafoe, Miller & Banister, An Epidemiological Study of Congenital Reduction Deformities of the Limbs, 31 Brit.J. Preventive & Soc. Med. 39 (1977). Dr. Buehler noted that the Smith article drew no strong conclusions but con-

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that absorption of the spermicide by the mother produced vascular disruption in

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tained data suggesting an association between spermicides and limb deficiencies.

(3) Jick, Walker, Rothman, Hunter, Holmes, Watkins, D'Ewart, Danforth & Madsen, Vaginal Spermicides and Congenital Disorders, 245 J. A.M.A. 1329 (1981). Dr. Buehler testified that the Jick article raised a serious question about an association between spermicides and limb defects.

(4) Buttar, Assessment of the Embryotoxic and Teratogenic Potential of Nonoxynol-9 in Rats Upon Vaginal Administration, 2 Toxicologist 39 (1982). Dr. Buehler noted that the Buttar study demonstrated that spermicides caused increased numbers of fetuses to be reabsorbed in rats and in mice, suggesting that spermicides can reach the fetus and destroy it.

the fetus that led to the birth defects.[7] The district court turned to the oral testimony of the various expert witnesses to resolve conflicts in the studies presented by each side. The court stated that it "found the studies to be inconclusive on the ultimate issue of whether the Product caused Katie Wells' birth defects." In facing this "battle of the experts," the district court was thus forced to make credibility determina-

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7 The absorption studies principally relied on by plaintiffs and plaintiffs' experts are as follows:

(1) Buttar, Transvaginal Absorption and Disposition of Nonoxynol-9 in Gravid Rats, 13 Toxicology Letters 211 (1982).

(2) Chvapil, Eskelson, Stiffel, Owen & Droegenmueller, Studies on Nonoxynol-9. II. Intravaginal Absorption, Distribution, Metabolism and Excretion in Rats and Rabbits, 22 Contraception 325 (1980).

nations to "decide the victor.[8] Ferebee v. Chevron Chemical Co., 736 F.2d 1529, 1535 (D.C.Cir.), cert. denied, ___ U.S. ___, 105 S. Ct. 545, 83 L. Ed. 2d 432 (1984).

We recognize, as did the Ferebee court, that

> a cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. As long as the basic methodology employed to reach such a conclusion is sound, such as use of tissue samples, standard tests, and patient examination, products liability law

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8 We are satisfied that the district court's extensive credibility determinations are not clearly erroneous. In assessing credibility the court looked at each expert's background, training, experience, and familiarity with the circumstances of this particular case. The court examined each expert's testimony in terms of its rationality and internal consistency in relation to all the evidence presented. The court also looked at each expert's demeanor and tone and searched for motives, biases, and interests that might have influenced opinion.

> does not preclude recovery until a "statistically significant" number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical.

Id. at 1535-36. The district court properly noted that "its ultimate focus was the birth defects suffered by Katie Wells. Plaintiffs' burden of proving that Katie Wells' defects were caused by the Product did not necessarily require them to produce scientific studies showing a statistically significant association between spermicides and congenital malformations in a large population." As the D.C. circuit noted in Ferebee, a distinction exists between legal sufficiency and scientific certainty. Id. at 1536. If the factfinder here is convinced that plaintiffs have proven to a reasonable degree of medical certainty, which is the legal standard employed in this case, that Ortho-Gynol caused Katie

Wells' arm, shoulder and hand defects, it does not matter in terms of deciding the case that the medical community might require more research and evidence before conclusively resolving the question. What matters is that this particular factfinder found sufficient evidence of causation in a legal sense in this particular case, and that that finding is nor clearly erroneous.

B. Failure to Warn

[3] Ortho next argues that the district court's liability finding based on Ortho's negligent failure to warn is clearly erroneous. Ortho contends that the district court misinterpreted Georgia law on the duty to warn, that the court's finding lacks substantial evidence in the record, and that the court improperly failed to consider two FDA review panels'

determinations that no warning is necessary for non-ionic surfactant spermicides. We reject Ortho's arguments and conclude that the district court's finding concerning Ortho's negligent failure to warn is not clearly erroneous.

Georgia law states that a manufacturer has a duty to warn of non-obvious foreseeable dangers from the normal use of its product. Rhodes v. Interstate Battery System, Inc., 722 F.2d 1517, 1519 (11th Cir. 1984); Kicklighter v. Nails by Jannee, Inc., 616 F.2d 734, 740 n. 4 (5th Cir. 1980). If a manufacturer has actual or constructive knowledge of potential dangers of a product, the manufacturer must warn purchasers at the time of sale and delivery. Id.; Beam v. Omark Industries, Inc., 143 Ga. App. 142, 237 S.E.2d 607, 610 (1977). Properly applying Georgia law, the district court found that

prior to July 1980 when Mary Maihafer purchased Ortho-Gynol, Ortho and actual or constructive knowledge that Ortho-Gynol might cause birth defects and thus was under a duty to warn purchasers, including Ms. Maihafer, of this risk. We conclude that this finding is not clearly erroneous in light of the evidence present in the record. Several studies existed piror to 1980 indicating that the use of spermicides might cause an increased risk of birth defects.[9] The district court found, and we agree, that these studies were available to Ortho. Plaintiffs' experts presented credible

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9 The three studies suggesting an association between spermicides and increased risk of birth defects prior to 1980 were the 1976 Oechsli study and the 1977 Smith study, see supra note 6, and a 1975 study, Vaginal Contraceptives -- A Time for Reappraisal?, Population Reports, Jan. 1975, at H-37.

testimony that a warning was necessary, that the duty to warn arose prior to Mary Maihafer's purchase of the product, and that the failure to warn proximately caused Katie Wells' birth defects.[10] The warning present on the Ortho-Gynol label and package insert at the time Mary Maihafer bought the product clearly did not mention the risk of birth defects.

The district court did consider the two FDA reports concerning non-ionic surfactant spermicides. The court, however, was not required to accept them as conclusive. An FDA determination that a warning is not necessary may be suffi-

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10 Plaintiffs' experts' Dr. Sutherland and Dr. Holbrook, see supra note 5, and Dr. Dick Gourley testified that Ortho should have warned of the risk of birth defects prior to 1980. Dr. Gourley is the dean of Mercer University School of Pharmacy in Atlanta, Georgia, and has published extensively on topics relating to pharmacy.

cient for federal regulatory purposes but still not be sufficient for state tort law purposes. See Ferebee, 736 F.2d at 1540. As we have stated previously, "compliance with regulatory standards may be admissible on the issue of care but does not require a jury [or judge as factfinder] to find a defendant's conduct reasonable." Dorsey v. Honda Motor Co., 655 F.2d 650, 656 (5th Cir. Unit B 1981), modified on other grounds, 670 F.2d 21 (5th Cir. Unit B), cert. denied, 459 U.S. 880, 103 S. Ct. 177, 74 L. Ed. 2d 145 (1982). We affirm the district court's findings concerning Ortho's negligent failure to warn.

C. Damages

Ortho asserts that the district court's determination of damages is clearly erroneous in that the court im-

properly awarded damages to Mary Maihafer for her emotional injuries. Ortho also argues that the court made a duplicative award of damages to Katie Wells for future lost earnings based on her total disability while at the same time making an award of damages to cure that total disability. We do not agree with Ortho's contention concerning Mary Maihafer's emotional injuries, but we conclude that the damage award to Katie Wells must be modified in light of the duplicative nature of part of it.

[4] The district court awarded Katie Wells $415,000 in damages for loss of future earnings. 615 F. Supp. 262. The court based this award on the testimony of plaintiffs' experts Dr. Joseph

Bussey and Dr. John Brown.[11] Dr. Bussey testified that "the impairments that [Katie Wells] had do constitute total and permanent disability for rating purposes." Dr. Brown analyzed Katie Wells' loss of future earnings from an economic perspective and stated that he was "assuming a hundred percent disability for purposes of [his] report." The court noted that Dr. Brown had produced a figure similar to the $415,000 award based on the assumption that Katie Wells would have completed college, that her "work life expectancy" would have been 27 91 years, and that she is totally

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11 Dr. Bussey is a general surgeon who formerly served as a consultant to a division of Johnson and Johnson, Ortho's parent company. Dr. Brown is an economist specializing as an actuary who serves as assistant professor of actuarial science at Georgia State University in Atlanta, Georgia.

disabled. In the court's estimation, the fact that Ortho had been found liable only for the defects of Katie Wells' left arm and shoulder and right hand would be offset by the court's finding that Katie Wells' "work life expectancy" likely would have been longer than Dr. Brown's conservative estimate of 27.91 years given her intelligence and her mother's educational achievements. The district court also awarded Katie Wells $1.2 million for future medical expenses associated with the birth defects proximately caused by Ortho-Gynol. The court based this award on "Dr. Buehler's testimony concerning Katie Wells' future medical expenses, including regular replacement of prosthetic devices and modification of work and living space." Finally, the court noted in a footnote to its order that it was including damages for loss of

earning capacity in the court's $3 million award to Katie Wells for pain and suffering.

We conclude that the $415,000 award to Katie Wells was duplicative and clearly erroneous for the following reasons. Though the court's order is somewhat vague concerning damages it is apparent that in making the award for loss of future earnings the court was assuming Katie Wells' total disability because both experts relied on by the court, Dr. Bussey and Dr. Brown, made that assumption. A conflict arises, however, when one considers that the court then made a further award to Katie Wells for future medical expenses including damages for the outfitting of Katie Wells with prosthetic devices and the modification of work space so she could actually work. Dr. Buehler, experienced in rehabilita-

tion medicine, indicated in his testimony that "based on my physical examination, even with that eye being, at least by the report, abnormal in vision, with her intelligence and the use of two arms and all, she could probably go up to the point to doing very important work with her arms, and she could have a very open career." Considering equipping her with prosthetic devices and training her to use a series of prostheses called myoelectrics, electrical-stimulated devices, Dr. Buehler testified that "we could pretty much return her to the potential of almost any occupation." Dr. Bussey also suggested that with prosthetics Katie Wells likely could develop skills sufficient to be employable. We conclude that an award for loss of future earnings based on Katie Wells' total disability is duplicative in that it conflicts with an

award for future medical expenses designed to make her employable and a further general damages award for loss of earning capacity included in the pain and suffering award. The testimony of Dr. Buehler and Dr. Bussey indicates that Katie Wells would be employable if she is equipped with prosthetic devices and sufficiently trained to use them, and we therefore modify the damage award to Katie Wells by reducing it by $415,000, striking the award for loss of future earnings. See Quality Foods, Inc. v. U.S. Fire Insurance Co., 715 F.2d 539, 543 (11th Cir. 1983) (recognizing our authority to reduce a judgement); see also Simpson v. United States, 322 F.2d 688, 693 (5th Cir. 1963) ("[w]here there are firm guidelines establishing the basic elements of the award and it can be computed with some degree of certainty as easily

by the appellate court as by the trial judge, it would be mere wasted motion to remand the cause for new findings"). The judgment is thus reduced to the following amounts:

(1)	Katie Wells:	
	(a) future medical expenses	$1,200,00
	(b) past and future pain and suffering	$3,000,000
(2)	Mary Maihafer:	
	(a) medical expenses of Katie Wells	$ 30
	(b) loss of earnings	$ 36,000
	(c) mental distress	$ 500,000

The case is remanded to the district court for entry of judgment in the amount of $4,736,030 in favor of plaintiffs.[12]

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12 Ortho also appeals the district court's denial of Ortho's motion to reopen the trial to consider two

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AFFIRMED and MODIFIED in part, REMANDED with instructions.

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recent studies concerning the relationship between spermicides and birth defects. We note that decisions concerning reopening of a direct case at trial are within the sound discretion of the district court. United States v. One 1972 44' Striker, Bonanza, 753 F.2d 867, 869 (11th Cir. 1985). We discern no abuse of that discretion in this case.

FILED IN CLERK'S OFFICE
U.S.D.C. - ATLANTA
JULY 29, 1985
LUTHER D. THOMAS, CLERK
BY: /s/
Deputy Clerk

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

KATIE LAUREL WELLS (Infant) by her mother and next friend, MARY MAIHAFER, and father, GARY S. WELLS,	:	
and	:	
MARY MAIHAFER (Individually),	:	Civil Action
Plaintiffs,	:	C82-1921A
vs.	:	
ORTHO PHARMACEUTICAL CORPORATION,	:	
Defendant.	:	

ORDER

Plaintiffs - Mary Maihafer and Gary S. Wells, on behalf of their infant daughter Katie Laurel Wells, and Mary Maihafer, individually - brought this products liability action against de-

fendant Ortho Pharmaceutical Corporation to recover damages arising from multiple birth defects suffered by Katie Wells. The central issues that emerged at trial were (1) whether Ortho-Gynol Contraceptive Jelly, a spermicide manufactured and marketed by defendant and allegedly used by plaintiff Mary Maihafer several months before and several weeks after Katie Wells was conceived, proximately caused these birth defects; and (2) whether defendant negligently failed to warn plaintiff Mary Maihafer that an increased risk of birth defects accompanied the use of its product.

At the parties' request, the case was tried before the Court without a jury.[1] After an exhaustive two-week

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1 Originally, this case was to have been tried before a jury. The Court

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trial with competent and well-prepared counsel for each side, the Court's decision was not an easy one. The medical and scientific evidence presented was in direct conflict. Still, the Court recognized then, and reiterates now, that its task was not to presume the expertise to resolve, once and for all, the dispute within the scientific community about the safety of spermicides. Rather, the Court's function was to render a legal decision, not a medical one. That is, the Court's duty was to weigh carefully the evidence that these parties presented to this

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specially set this case on its calendar for a specific time period, based on the parties' initial estimates of the length of time required. The parties later revised their estimates upward and agreed to waive a jury trial so that the case could be tried within the time set aside by the Court.

Court in the trial of this case and to determine with reference to the facts of the case at hand whether plaintiffs had satisfied their burden of proving that they were entitled to the relief sought.

At trial the key evidence was the testimony of highly qualified expert witnesses and various medical and scientific studies. In considering this evidence, the Court kept in mind plaintiffs' burden of proof: plaintiffs could not recover if the Court found that there was only a "bare possibility" that the spermicide caused these birth defects or that other theories of causation were equally plausible. See Maddox v. Houston County Hospital Authority, 158 Ga. App. 283, 284 (1981). Rather, to authorize recovery plaintiffs' evidence must have shown to a "reasonable degree of medical certainty" that defendant's product was responsible.

Parrott v. Chatham County Hospital Authority, 145 Ga. App. 113, 115 (1978); see also Defendant's Trial Brief at 3.

The testimony of plaintiffs' and defendant's experts conflicted on several crucial points. Experts on each side testified that, to a reasonable degree of medical certainty, their side's theory of the case was correct. Attempting to resolve these direct conflicts in the experts' opinions, throughout the trial the Court regularly examined daily transcripts of much of the expert testimony and spent an entire weekend reviewing the studies introduced. Although some of the studies suggested a connection between spermicides and birth defects, overall the studies failed to show conclusively whether or not the spermicide caused any or all of the birth defects suffered by Katie Wells. The Court emphasizes,

however, that plaintiffs' ultimate burden was not to produce an unassailable scientific study which proves that spermicides have caused birth defects in rats, rabbits, or members of a large group health plan, but rather to show from all the evidence presented, to a reasonable degree of medical certainty, that the spermicide caused some or all of Katie Wells' birth defects.

The Court's decision, therefore, turned on the oral testimony of a variety of expert witnesses whose opinions often were diametrically opposed on the major issues presented in the case. In assessing the credibility of these witnesses, the Court considered each expert's background, training, experience, and familiarity with the circumstances of this particular case; and the Court evaluated the rationality and internal consistency of each

expert's testimony in light of all the evidence presented. The Court paid close attention to each expert's demeanor and tone. Perhaps most important, the Court did its best to ascertain the motives, biases, and interests that might have influenced each expert's opinion.

With few exceptions, the Court found the testimony of plaintiffs' experts generally to be competent, credible, and directed to the specific circumstances of this case. The testimony of defendant's experts, in contrast, often indicated bias or inconsistency. Primarily because the Court found plaintiffs' expert testimony to be far more credible than defendant's, at the conclusion of trial the Court announced that plaintiffs had carried their burden of proving that the spermicide proximately caused some, but not all, of Kate Wells'

birth defects and that defendant had been negligent in failing to warn plaintiff Mary Mahaifer of this danger. As a result, the Court awarded damages to plaintiffs Katie Wells and Mary Mahaifer. The following discussion explains in detail how the Court arrived at this decision from the evidence presented at trial and sets forth the Court's findings of fact and conclusions of law in accordance with Rule 52, Fed.R.Civ.P.

Plaintiffs' Contentions

Plaintiff Mary Maihafer, the mother of plaintiff Katie Wells, is a thirty-two year old college instructor who, plaintiffs contended, has no family history of birth defects and who in 1979 gave birth to a child with no birth defects. According to plaintiffs, Gary S. Wells, the father of Katie Wells, also has no family history

of birth defects and is the father of a child born in 1974 without birth defects.

In July 1980, Ms. Maihafer obtained from her gynecologist a prescription for a diaphragm to be used for contraception and a sample tube of Ortho-Gynol Contraceptive Jelly ("the Product"). At that time, plaintiffs contended, a nurse instructed her on the proper use of the diaphragm and spermicidal jelly, and Ms. Mahaifer read the "Directions for Using Ortho-Gynol Contraceptive Jelly," which accompanied the Product.[2]

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2 The only language included with these directions in this "package insert" that expressed any type of warning was the following:

PRECAUTION
If you have been advised against pregnancy for medical reasons, your birth control method should be thoroughly discussed with your physician so that both you and your physician are satisfied that the

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Plaintiffs alleged that Ms. Maihafer had used the diaphragm and Ortho-Gynol Contraceptive Jelly in accordance with these instructions every time she had sex with Gary Wells from the time the diaphragm was prescribed in late July 1980 until Mid-November 1980. Transcript at 80-81. Notwithstanding these precautions, Ms. Maihafer missed her menstrual period that

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> method you have selected is right for you.
>
> ADVERSE REACTIONS
> Occasional burning and/or irritation of the vargina or penis have been reported. If this occurs, discontinue use and consult your physician.
>
> WARNING
> Keep out of reach of children.
>
> Remember, no method of birth control can absolutely guarantee against pregnancy. For maximum protection, all methods - including these - must be used according to the directions.

was due to occur around November 1, 1980, and later discovered that she had become pregnant in October 1980.

On July 1, 1981, Ms. Maihafer gave birth to plaintiff Katie Wells, who was born with the following birth defects: (1) a cleft lip; (2) an abnormal formation and shortening of her right hand; (3) the absence of the distal joint of her right ring finger; (4) the complete lack of a left arm; and (5) only partial development of the left clavicle and shoulder. Later Kate Wells was diagnosed as also suffering from hypoplasia of the right optic nerve, which according to plaintiffs has made her almost ninety percent blind in that eye. Transcript at 11.

Plaintiffs filed this action on September 1, 1982, seeking to recover

for damages to both Katie Wells and Mary Maihafer.[3] The complaint stated causes of action for negligence, strict products liability, intentional tort, and breach of warranty.[4] Plaintiffs asserted that

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3 With respect to Katie Wells, plaintiffs prayed for damages for her past and future medical expenses, permanent disability, past and future pain and suffering, and "loss of earning capacity." Plaintiff Mary Maihafer sought damages for physical pain and suffering, mental anguish, "loss of earning capacity," and loss of services of Katie Wells. The claims for "loss of earning capacity" actually were claims for loss of earnings, and the Court treated them as such. Both these plaintiffs also sought punitive damages.

4 Plaintiffs initially presented three theories of negligence:

(1) negligent failure to warn that the Product does not always prevent conception;

(2) negligent failure to warn that if conception occurs through the spermicide's failure, any child born would face an increased risk of serious birth defects; and

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the spermicide's active ingredient, a non-ionic surfactant that works to break down sperm cell membranes, caused these birth defects through one of the following "mechanisms":

> (1) injury to a sperm that ultimately fertilizes an egg;
>
> (2) injury to an unfertilized egg;
>
> (3) injury to a fertilized egg or zygote; or
>
> (4) injury to the developing fetus, either by direct contract with the fetus or by absorption by the mother.

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> (3) negligence per se by violation of the labelling provisions of the Food, Drug, and Cosmetic Act.
>
> At the conclusion of trial, the Court granted defendant's motion for involuntary dismissal of plaintiff's claims for negligence per se; negligent failure to warn that the Product does not always prevent conception; intentional tort; breach of warranty; punitive damages; and two claims added by plaintiffs at trial, fraud and "conspiracy." Transcript at 1717-21.

Transcript at 21-22. Moreover, plaintiffs alleged that, at the time Mary Maihafer purchased and used the Product, defendant knew or should have known of certain studies that were available to the scientific community linking the use of spermicides to birth defects in the children of mothers who used spermicides around the time of conception.

According to plaintiffs, defendant's actual or constructive knowledge of this increased risk imposed on defendant a duty to warn health professionals and prospective users of this risk by placing a warning on the Product. Plaintiffs argued that defendant's failure to warn constituted a defect in the Product and thus established defendant's liability under a strict products liability theory. Further, plaintiffs maintained that the failure to warn was also a basis for

finding defendant negligent. Transcript at 13. Finally, plaintiffs maintained that they were entitled to punitive damages because defendant's failure to warn was part of a conscious decision to protect its market share. Transcript at 34-35.

Defendant's Contentions

Defendant vehemently denied any association between the use of Ortho-Gynol Contraceptive Jelly and birth defects. Defendant pointed out that the Product's active ingredient, a non-ionic surfactant called p-diisobutylphenoxy-polyethoxyethanol or octoxynol-9, is almost identical to non-ionic surfactants used by other manufacturers of spermi-

cides.[5] Since 1950, defendant has sold the Product in its present form to millions of women.

Defendant maintained that the Product is safe and effective when properly used. Defendant suggested that Ms. Maihafer may not have used the spermicide in strict accordance with the instructions. Defendant also pointed out that the Product carried a warning that no form of birth control is one hundred percent effective. Transcript at 36-37.

According to defendant, no additional warning was or is necessary. Defendant argued that at the time of Kate Wells' conception in the fall of 1980, no published reports or studies had

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5 According to the expert testimony at trial, one other non-ionic surfactant that is essentially similar to octoxynol-9 is nonoxynol-9.

concluded that spermicides cause birth defects; further, according to defendant, it had received no other complaints nor had access to any other evidence suggesting a link between its Product and birth defects.

Defendant argued that, on the contrary, "[t]he overwhelming weight of the credible scientific evidence has established that use of such products does not cause birth defects." Consolidated Pretrial Order at 9. Defendant criticized studies relied on by plaintiffs' experts as "flawed" and "not scientifically reliable." Defendant's Proposed Findings of Fact and Conclusions of Law at 2. According to defendant, numerous respected scientists have conducted extensive testing and critical review of non-ionic surfactants and have concluded that the Product is safe and effective. Consolidated Pretrial Order

at 9. Defendant pointed out that at least one select panel appointed by the government has concluded that the Product should carry no warning that it might cause birth defects. Id.

Finally, defendants argued that even if plaintiffs succeeded in proving a causal link between the Product and Katie Wells' birth defects, defendant had no duty to place a warning on the Product in 1980 because of the absence of any reliable information at that time connecting spermicides and birth defects. Thus, according to defendant, the Product was not defective, defendant had not been negligent, and the failure to provide any such warning was not the result of a conscious marketing decision that might support a claim for punitive damages. Transcript at 46-47.

The Evidence at Trial

A. Mary Maihafer

Plaintiff Mary Maihafer testified on direct examination consistently with plaintiffs' theory of the case outlined above. Ms. Maihafer testified positively that she had used the diaphragm and spermicidal jelly according to the instructions every time she and Gary Wells had sex from late July until mid-November 1980. She further stated that she had continued to use the Product for one to two weeks after she missed her menstrual period of November 1, 1980. Transcript at 76, 80-81. Ms. Maihafer also mentioned that several months into this pregnancy she had used the prescription drug Decadron for bronchitis and some prescribed anti-

biotics[6] for an ear infection. Transcript at 63-64. In addition, she testified that after Katie Wells' birth, she interrupted her college teaching career for two years to take care of the child. Transcript at 963. On cross-examination, Ms. Maihafer admitted that she had known, at the time she obtained the diaphragm and spermicide, that diaphragms are not one hundred percent effective in preventing conception. Transcript at 122.

B. Gary Wells

Gary Wells testified that, to his knowledge, Mary Maihafer used the diaphragm and spermicide every time they had sex from the time she obtained it until mid-November 1980. Transcript at 151. Counsel for both sides questioned him

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6 Other evidence introduced by plaintiffs identified this drug as Amoxicillin.

about his use of drugs. He testified that he had used LSD once in 1971, amphetamines three or four times in 1979, and methaqualone in two or three doses in 1979. Further, he stated that he had smoked marijuana on infrequent occasions from 1969-72 and that he may have smoked marijuana once or twice in 1980 during the time he dated Mary Maihafer. Transcript at 147-51, 155-57.

C. Dr. Bruce Buehler

Plaintiffs' primary expert witness was Dr. Bruce Buehler, who is an associate professor of pediatrics and pathology at the University of Nebraska Medical Center, the director of the Center for Human Genetics, and the director and dean of the Meyer Children's Rehabilitation Institute. Dr. Buehler is board-certified in pediatrics, chemical genetics, and biochemical and metabolic genetics. His

research area is biochemical teratology, the study of the effects of drugs and environmental agents on developing fetuses. Transcript at 203. The list of Dr. Buehler's credentials is long and impressive.[7]

Dr. Buehler testified that the Meyer Children's Rehabilitation Institute each year handles approximately 25,000 visits by handicapped persons from birth through

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7 Dr. Buehler is the recipient of numerous academic appointments; several grants, including the "Genetics and Birth Defects Service Grant"; honors and awards for teaching pediatrics and genetics and rehabilitation medicine; memberships in various professional societies; and assignments to a number of medical committees and boards. Dr. Buehler has published approximately fifty articles and abstracts, the majority in the field of biomedical teratology, including studies of upper limb anomalies. Further, Dr. Buehler has spent years treating and studying patients with handicapping disorders. Transcript at 212-19.

age sixty. The Institute, which employs an estimated ninety professionals who work with handicapping disorders, has a national reputation that attracts patients from all over the country. Transcript at 204-06.

Dr. Buehler had examined Kate Wells in person, as opposed to merely viewing her medical records. Before testifying about his findings in the examination and his conclusions that followed, Dr. Buehler explained what a geneticist looks for in an examination to determine the cause of birth defects, and he demonstrated with Katie Wells in court certain aspects of the examination.

The doctor testified that in examining patients with birth defects, a geneticist attempts to determine at what stage of fetal development the defects or abnormalities occurred. He stated that because

genetic problems "tend to do their dirty work" from the moment of conception, they result in abnormalities in the body that are symmetrical. On the other hand, Dr. Buehler explained, birth defects tend to be asymmetrical when they are caused by the environment, drugs, and a few genetic problems. Thus, in examining Katie Wells, Dr. Buehler testified that the and a colleague spent much time studying the symmetry of her body and the placement and size of her body parts. Transcript at 220-22.

Dr. Buehler explained his findings as he re-enacted portions of the examination in court with Katie Wells. What the doctor found most significant, and what the Court partially observed, was the condition of Katie's left shoulder: the shoulder was totally smooth, the shoulder blade and scapula were half

their normal size, and the size of the muscles was normal. Transcript at 227-28. Dr. Buehler testified that although most limb deficiencies show some attempt at making an arm or finger - such as a hand or piece of tissue attached to the shoulder - the complete smoothness of this shoulder was rare and suggested total disruption of the limb bud. He also found surprising the normal musculature of a shoulder with no arm. Transcript at 230.

Dr. Buehler considered and rejected the possibility that the shoulder defects were caused by "amniotic banding" that cut off the arm; if a band had been present, he stated, the clavicle and scapula behind the band would have been normal. Moreover, the hospital delivery records included no description of amniotic banding. He also rejected as inconsistent with his experience the possibility that the limb had been

trapped in the womb and absorbed or destroyed by the body. He concluded that the limb defect must have been caused by a vascular disruption - an interruption in the blood supply to the developing limb. According to Dr. Buehler, the interruption prevented the development of a left arm and provided insufficient blood supply for the clavicle and scapula to reach their normal size. Transcript at 230-32, 242.

Similarly, the doctor concluded that the defects of the right hand probably were caused by a vascular disruption. Although Dr. Buehler observed that the wraps of "fiber material" around Kate Wells' fingers gave the appearance of amniotic banding, he rejected this explanation because the missing portion was in the middle - not at the end - of Katie Wells' finger. He stated that the missing part must have once been there but

disappeared, an occurrence explainable only by loss of blood supply and reabsorption. Dr. Buehler further testified that the formation of the fingers was inconsistent with amniotic banding, with which "you would expect essentially amputation." Transcript at 232.

Although Dr. Buehler testified definitively that vascular disruption had caused the birth defects of Katie Wells' shoulder and hand, he would not attribute her other defects to the same cause. He testified that although he could not rule out the possibility of vascular disruption, he did not have "enough data to make a cleft lip a vascular accident as I do with limb deformities." Transcript at 233. With respect to the hypoplasia of the optic nerve, Dr. Buehler stated as follows:

> It is much easier to explain eye formation and optic nerve

> formation on a vascular basis than it would be for me for a cleft [lip]. That is not what I ruled out or ruled in. I have not included that in my opinion because I have focused on the arms, which are the most comfortable to me.

Transcript at 234. That Dr. Buehler was careful in limiting his opinion to matters within his area of expertise greatly enhanced his credibility in the view of the Court.

Dr. Buehler identified the most likely cause of the vascular disruption in this case as the Product. He testified that diabetes, one possible source of the irritation of the vascular supply, had been ruled out in this family. Instead, Dr. Buehler stated that scientific studies supplied to him by plaintiffs and other studies he had reviewed on his own suggested that exposure to spermicides could produce a higher risk of limb defects. The doctor went on to testify that he was

"more comfortable with his opinion and [did] not require the literature as strongly" because Mary Maihafer had used the spermicide not only at conception, but also through the time of development of the limb buds during the first few weeks after conception. Transcript at 243-44, 276.[8] Dr. Buehler elaborated on this conclusion, recalling that certain studies have suggested that spermicides can be absorbed and find their way to the fetal site, where they can irritate or otherwise affect fetal development. Dr. Buehler further testified that he rejected the possibility that LSD and

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8 With the aid of a slide presentation, Dr. Buehler explained that the limb buds are visible four-and-one-half to five weeks after conception. He stated that destruction of the limb bud would have to have occurred "much earlier" than four weeks after conception for a smooth shoulder such as Katie's to result. Transcript at 275-76.

other drugs taken by Gary Wells on occasion or Decadron and Amoxicillin taken by Mary Maihafer during this pregnancy could have caused these birth defects.

Dr. Buehler also discussed several pertinent studies and articles that he had reviewed prior to trial. The first was the 1976 Oechsli study,[9] which was prepared for the National Institutes of Health (NIH). According to Dr. Buehler, NIH generally selects excellent researchers, and epidemiologists and teratologists generally rely heavily on

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9 Oechsli, Studies of the Consequences of Contraceptive Failure (Apr. 8, 1976) (unpublished study). The study was the "Final Report for Contract NO1-HD-5-2816" for the Contraceptive Evaluation Branch, Center for Population Research, National Institute of Child Health and Development. The author was Frank W. Oechsli, Ph.D., of the School of Public Health at the University of California, Berkeley.

such data when available. Dr. Buehler described the Oechsli study as indicating a "question" and possible relationship" between spermicides and birth defects. Dr. Buehler further noted that the unpublished Oechsli study was cited to in the March 1980 Harlap article,[10] which was published in a well-respected journal. In Dr. Buehler's opinion, it appeared that the Oechsli study would have been available to the general medical community. Transcript at 247-54.

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10 Harlap, Spontaneous Foetal Losses in Women Using Different Contraceptives around the Time of Conception, 9 Int'l. J. Epidemiology, Mar. 1980, at 49. In citing the Oechsli study, however, the Harlap article disagreed with it: "Previous reports [citation to Oechsli] of an excess risk associated with spermicides are not borne out by this study." Id. at 56.

Next, Dr. Buehler addressed the 1977 Smith article.[11] Although Dr. Buehler observed that the Smith article drew no strong conclusions, he pointed out that it contained data suggesting an association between spermicides and limb deficiencies. Based on these studies, Dr. Buehler concluded that in the 1970's the existence of a potential problem with spermicides was known. Transcript at 254-56.

Dr. Buehler also discussed the 1981 Jick article,[12] which he stated was published in the well-respected Journal of the American Medical Association. According

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11 Smith, An Epidemiological Study of Congenital Reduction Deformities in the Limbs, British Journal of Preventive and Social Medicine, 1977, at 39.

12 Jick, Vaginal Spermicides and Congenital Disorders, Journal of the American Medical Association, Apr. 3, 1981, at 1329.

to Dr. Buehler, this article raised a "serious question" about an association between spermicides and limb defects. He testified that after the publication of this article, he began recommending that pregnant women undergo ultrasound testing for fetal limb deficiencies twelve to eighteen weeks after conception. Transcript at 259-62.

The next study that Dr. Buehler addressed was the 1982 Buttar study of the potential embryotoxic and teratogenic effects of the non-ionic surfactant nonoxynol-9.[13] Dr. Buehler testified that

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13 Buttar, Assessment of the Embryotoxic and Teratogenic Potential of Nonoxynol-9 in Rats Upon Vaginal Administration, 2 The Toxicologist 39 (1982). This study concluded as follows: "The results suggest that single vaginal application of [nonoxynol-9] is embryolethal and fetocidal but nonteratogenic in the rat at a dose approximately ten times higher than that recommended for controlling conception in women." Id. at 40.

this study provided a strong basis for his opinion that the spermicide was the most likely cause of Katie Wells' arm and hand defects because it showed that the spermicide caused an increased number of fetuses to be reabsorbed in rats and in mice. In Dr. Buehler's view, the "embryolethality" shown by this study was a "very strong suggestion" that the spermicide can reach the fetus and destroy it, a result that suggests the spermicide is teratogenic, notwithstanding the author's stated conclusion. Transcript at 268-70.

Finally, Dr. Buehler addressed the 1982 Jick article.[14] He testified that this article showed a higher miscarriage rate in mothers who, according to Jick's

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14 Jick, Vaginal Spermicides and Miscarriage Seen Primarily in the Emergency Room, 2 Teratogenesis, Carcinogenesis, and Mutagenesis 205 (1982).

definition, used spermicides. In Dr. Buehler's opinion, this increased miscarriage rate was another suggestion that spermicides are teratogenic. Transcript at 270-73.

Turning from causation to consequences, Dr. Buehler addressed the future medical expenses that would accompany Katie Wells' birth defects. Based on his experiences with rehabilitation medicine, the doctor testified that prosthetic devices and adaptive equipment "to maximize [Katie Wells'] potential" would cost at least one to one-and-a-half million dollars. Transcript at 282-82.

Defense counsel conducted a thorough and probing cross-examination of Dr. Buehler. When asked whether the 1981 Jick study proved that spermicides caused the limb reduction defects that Jick found. Dr. Buehler answered in the negative,

but explained that "there isn't any teratogen study that has proven 'yes' or 'no.' It is an improbability risk. This raises a probability question." Transcript at 351. Even after taking into account all the concerns raised by defense counsel, Dr. Beuhler concluded, with a reasonable degree of medical certainty, that the spermicide had caused the defects in Kate Wells' shoulder and hand. Transcript at 327.

The Court found Dr. Buehler to be the most credible of all the witnesses presented in this case. His credentials and experience in biochemical teratology were impressive. Unlike defendant's experts, he had personally examined Katie Wells. His uncontradicted testimony was that he formed no opinion until after this examination. His opinion at trial was the same as the opinion that he pre-

viously had offered at his deposition, which defense counsel conducted within an hour of his examination of Katie Wells. That Dr. Buehler limited his testimony to the area of his expertise - limb defects - and would not say that all Katie Wells' defects were caused by the spermicide, made his opinion even more believable. His detailed explanation of how he had ruled out other possible causes demonstrated that his opinion was the product of a careful, methodical reasoning process, not mere speculation. His demeanor as a witness was excellent: he answered all questions fairly and openly in a balanced manner, translating technical terms and findings into common, understandable language, and he gave no hint of bias or prejudice. In short, this witness could hardly have been more credible.

D. Dr. Earl Sutherland

Another expert who testified for plaintiffs was Dr. Earl Wilbur Sutherland, III. Dr. Sutherland, who has a Ph.D. in pharmacology and an M.D., is an assistant professor of medicine in the departments of internal medicine and clinical pharmacology at the University of Colorado School of Medicine in Denver. Since 1980 he has been Medical Director of the Rocky Mountain Drug Consultation Center, which offers information about therapeutic drugs to consumers and health professionals. He is board-certified in internal medicine, and he actively practices in that field. Dr. Sutherland also worked with NIH for several years beginning in 1969. Transcript at 523-39.

Dr. Sutherland's testimony concerned both key issues in this case: the causation of Katie Wells' birth defects and

the adequacy of defendant's warning. Addressing causation, he testified that non-ionic surfactants work by disrupting the lining of sperm cells, thus either killing or immobilizing them. Transcript at 540-42. According to Dr. Sutherland, non-ionic surfactants are toxic to many other cells as well. He testified that, based on his research of published and unpublished materials, in his opinion spermicides have a "definite role" in causing birth defects. Transcript at 543.

Although Dr. Sutherland could not identify with certainty the "mechanism" by which spermicides can cause birth defects, he pointed out that mechanisms have not been discovered for some drugs - such as thalidomide - that are known to cause congenital malformations. Dr. Sutherland did suggest several possible

mechanisms: (1) that the spermicide may have injured a sperm which nonetheless fertilized the egg, resulting in abnormal development of the fetus; (2) that the spermicide may have injured the unfertilized egg; or (3) that the spermicide may have injured the fertilized egg. Transcript at 544, 565-66. Further, Dr. Sutherland stated that non-ionic surfactants can cause vascular disruption by irritating or injuring small blood vessels. Transcript at 545-46.

Based on his personal examination of Katie Wells, his review of the relevant medical records in this case, his reading of the literature, and his knowledge and experience as a physician and pharmacologist, Dr. Sutherland concluded that the non-ionic surfactant in the Ortho-Gynol Contraceptive Jelly caused Katie Wells' birth defects. Transcript at

565-66. He explained that non-ionic surfactants are "readily absorbed" by the mother's body[15] and, because they are toxic to a variety of cells, they create a potential for injury not only to spermatozoa, but also to the ovum, the fertilized egg, and the fetus. Dr. Sutherland also noted the existence of clinical reports suggesting an association between non-ionic surfactants and birth defects. Transcript at 565-568. Therefore, according to Dr. Sutherland, the spermicide

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15 On a re-direct examination Dr. Sutherland stated with a reasonable degree of medical certainty that, in his opinion, the non-ionic surfactant in the Product is absorbed by the body of the woman using the Product. The basis for his opinion included these studies: Buttar, Transvaginal Absorption of Spermicides, 13 Toxicology Letters 211 (1982); and Chvapil, Studies on Nonoxynol-9. II. Intravaginal Absorption, Distribution, Metabolism and Excretion in Rats and Rabbits, 22 Contraception 325 (1980). Transcript at 664.

had several opportunities to cause these birth defects in Katie Wells, and the lack of certainty about precisely which mechanism or mechanisms were involved was consistent with the uncertainty surrounding how certain known teratogens work. Transcript at 567.

Addressing the issue of failure to warn, Dr. Sutherland stated that his background had made him familiar with the pharmaceutical industry's customary practices regarding warnings and also with the procedures followed in studies and reports made for NIH. He testified that the 1976 Oechsli study, which raised questions about a possible relationship between spermicides and birth defects, was performed under an NIH contract and that, although the study was never formally published, it would have been available to the public and the pharmaceutical

industry long before Mary Maihafer purchased and used the spermicide in 1980.[16] Transcript at 553-58. According to Dr. Sutherland, the Oechsli study employed

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16 Dr. Sutherland testified that the Oechsli study was performed in response to a "Request for Proposal" (RFP) by the National Institute of Child Health and Development. He stated that RFPs are made known to the general public through word of mouth, through government publications, and through private services that publish RFPs. According to Dr. Sutherland, "It's a well known thing [that] when an RFP comes out, most people who are interested in it actually already know about it." Transcript at 551-555. His testimony suggested that defendant should have known that the Oechsli study was forthcoming even before the study was underway.

Dr. Sutherland further testified that once completed, the Oechsli study would have been available to the public under the Freedom of Information Act. Moreover, according to Dr. Sutherland, the Oechsli study was referred to in the Harlap article published in 1980, several months before Ms. Maihafer began using Ortho-Gynol Contraceptive Jelly. Transcript at 556-58.

standard, widely-accepted techniques. He also stated that the pharmaceutical industry routinely relies on NIH studies. Transcript at 559-60.

Because the Oechsli study and the 1977 Smith study indicated a "serious potential" that spermicides increase the risk of fetal injury, and because both studies were available to defendant before Mary Maihafer began using the Product, Dr. Sutherland concluded that the warning on the label of the Product was inadequate. In his opinion, the Product should have carried a warning that a user should discontinue use if she suspects she is pregnant and that the Product might increase the risk of fetal malformations. Transcript at 562. This opinion, he stated, was based on the studies linking spermicides with birth defects, the known toxicity of the sper-

micide, and the evidence that non-ionic surfactants are absorbed by mothers using spermicides. Dr. Sutherland emphatically concluded that defendant's failure to provide such a warning fell beneath the customary standard of care in the pharmaceutical industry. Transcript at 563.

Finding Dr. Sutherland more than qualified to address the issues of causation and failure to warn, the Court judged him to be a credible witness. Without being dogmatic, he was positive and emphatic in his conclusions that the spermicide caused Katie Wells' birth defects and that the warning on the Product was inadequate. His manner suggested objectivity and openness. For example, he readily admitted that he could not pinpoint the mechanism by which the spermicide caused these birth defects. Furthermore, his conclusions withstood a

rigorous cross-examination, and he showed no sign of bias or prejudice that might lead the Court to discount his opinion.

E. Dr. Joseph Bussey

Plaintiffs also called as a witness Dr. Joseph Gibson Bussey, a general surgeon who had been a consultant to a division of Johnson and Johnson, the parent company of defendant Ortho Pharmaceutical Corporation. Dr. Bussey testified that, in his opinion, the spermicide had caused Katie Wells' birth defects and that the warning on the label of the Product was inadequate. Transcript at 459, 463.

Dr. Bussey's background also included experience in evaluating disabilities: he was a founding member of the National Association of Disability Evaluating Physicians. Transcript at 430. Based on his examination of Katie Wells and his review of her medical re-

cords, Dr. Bussey testified that, in his opinion, Katie Wells is totally and permanently disabled. Transcript at 470.

With the exception of his testimony concerning the degree of Katie Wells' disability, the Court did not place much reliance on Dr. Bussey's testimony. Although Dr. Bussey appears to have an excellent background in surgery, his practice only occasionally involves obstetrics and gynecology, a fact underscored by defense counsel on cross-examination. Further, none of his research or writing has dealt with epidemiological studies or the causes of birth defects.

Another fact detracted from Dr. Bussey's credibility: he testified that he first became interested in a connection between spermicides and birth defects when his wife had a spontaneous abortion after using a spermicide manu-

factured by defendant. Transcript at 432-37. Because of the inherent potential for bias or prejudice, the Court has given little weight to Dr. Bussey's testimony concerning causation and failure to warn.

F. Dr. John Holbrook

Another expert witness who testified for plaintiffs was Dr. John Marshall Holbrook, the Director of Research and Associate Professor at Mercer University School of Pharmacy. Dr. Holbrook's credentials include a B.S. in Pharmacy and a Ph.D. in Pharmacology. His background in teaching and publishing has included, among other things, the toxic effects of certain drugs on the body. Transcript at 163-72.

Dr. Holbrook described from his perspective as a pharmacologist how spermicides containing non-ionic surfactants

work. He explained that non-ionic surfactants are detergents that disrupt and inactivate sperm by breaking down their cell walls. By this very mechanism, Dr. Holbrook stated, non-ionic surfactants cause irritation. Transcript at 176-78.

In Dr. Holbrook's opinion, a "definite relationship" exists between the use of spermicides and fetal malformations. Transcript at 710-11. Dr. Holbrook based this conclusion on various articles and studies dating as far back as 1975 that suggested the existence of such a link. The earliest of these, which appeared in January 1975,[17] indicated to Dr. Holbrook that there had been little evaluation of the damage which spermicides might pro-

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17 Vaginal Contraceptives - A Time for Reappraisal?, Population Reports, Jan. 1975, at H-37.

duce and that spermicides might cause birth defects. Transcript at 181-83.

The 1976 Oechsli study, in Dr. Holbrook's view, was a "strong suggestion" that the use of spermicides could lead to serious birth defects. Transcript at 191. Similarly, Dr. Holbrook testified that the 1977 Smith article contained indications that spermicides might be teratogenic. Transcript at 704-05.

According to Dr. Holbrook, other articles and studies[18] published after

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18 For example, Dr. Holbrook noted that the 1980 Warburton abstract, Environmental Influences on Rates of Chromosome Anomalies, American Journal of Human Genetics (1980), identified spermicides as a possible factor in spontaneous abortions. This finding suggested to Dr. Holbrook that spermicides may be teratogenic. The Buttar absorption article, see supra note 15, led Dr. Holbrook to conclude that spermi-

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Mary Maihafer began using the spermicide also contributed to his conclusion of a "definite relationship" between spermicides and birth defects. Still, in his opinion, the scientific literature available before July 1980 should have prompted Ortho Pharmaceutical Corporation to warn

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cides are absorbed by the user's body and can find their way to the fetus. Transcript at 705-07. Finally, the Buttar abstract on the potential embryotoxic and teratogenic effects of nonoxynol-9, see supra note 13, suggested to Dr. Holbrook that non-ionic surfactants can damage the fetus during the early stages of gestation. Transcript at 708-09.

It is noteworthy that Dr. Holbrook found a "definite relationship" between spermicides and birth defects even though he, like Dr. Sutherland, could not identify the precise "mechanism" by which spermicides can cause birth defects. Dr. Holbrook did suggest several possible mechanisms that were essentially the same as those identified by Dr. Sutherland. Transcript at 710-712.

physicians, pharmacists, and consumers of a possible increased risk of fetal malformations "at the very, very first hint of a problem with the compound." Transcript at 718-19. Ortho's failure to issue any such warning was contrary to the ordinary custom in the pharmaceutical industry of monitoring the available medical literature and warning of potential problems with products, according to Dr. Holbrook. Transcript at 715-19.

Dr. Holbrook further addressed whether Mary Maihafer's consumption of alcohol during pregnancy or Gary Wells' past drug use might change his opinion. He testified that neither of these facts would alter his conclusion concerning the relationship between spermicides and birth defects.

The Court found Dr. Holbrook to be a credible witness. His background in

pharmacology gave credence to his testimony concerning the potential pharmacological effects of spermicides and the customary procedures concerning warnings in the pharmaceutical industry. His demeanor on both direct and cross-examination indicated that he was giving his honest appraisal of the issues of causation and failure to warn.

G. Dr. Dick Gourley

A most persuasive witness for plaintiffs on the issue of failure to warn was Dr. Dick Gourley. Dr. Gourley's background and credentials are extensive: formerly a full professor and chairman of the Department of Pharmacy at the University of Nebraska, Dr. Gourley presently is a full professor and Dean of Mercer University School of Pharmacy. He has published at least thirty-seven articles and six to eight chapters in books relat-

ing to pharmacy, including a chapter in the "Handbook of Nonprescription Drugs" (the "O.T.C. Handbook"), a compendium of chapters on nonprescription products published by the American Pharmaceutical Association. Additionally, Dr. Gourley is a senior reviewer of the O.T.C. Handbook and serves on the editorial boards of two pharmaceutical journals. He has received numerous grants and contracts from private foundations, government agencies, and pharmaceutical companies. Most significantly, Dr. Gourley has served as an advisor or consultant to many major pharmaceutical firms, and in this capacity his wide range of responsibilities has included advising these drug companies what information should be included in package inserts and drug information packets. Transcript at 845-864.

Dr. Gourley stated forcefully that the warning on the label of Ortho-Gynol Contraceptive Jelly is insufficient. He testified that "as soon as the first study is done and any information that is provided...gives the hint that there is a possibility of a drug causing birth defects," the label should be changed to include a warning. Transcript at 870. According to Dr. Gourley, defendant should have warned that its Product carries an increased risk of birth defects soon after that possibility was suggested by the Oeschsli study in 1976, and no later than the publication of the Smith study in 1977. Transcript at 870, 876-77. He explained that, according to his experience, firms in the pharmaceutical industry closely watch the workings of the scientific community - including NIH - for any information concerning

their products because this information affects their business.

In Dr. Gourley's view, the Smith study, which was published in 1977, certainly was available to defendant that same year. Further, he testified that the unpublished 1976 Oechsli study also would have been available to defendant:

> The Oechsli study is a study of N.I.H., and studies such as this become public. Now, [it]'s not necessary that it has to be published in a journal for industry to get ahold of something like this. They may not have had it on April the 8th, 1976, but, if they didn't have it within a few months of that, then somebody was asleep at the wheel.

Transcript at 871-73.

In Dr. Gourley's opinion, an adequate warning on the Product's label might be as simple as the following: "Do not use in case of pregnancy, and if you become pregnant while using the product, please contact or consult your physician."

Transcript at 868. Dr. Gourley emphasized the importance of a patient's "right to know":

> [O]ur attitude towards patients has changed dramatically in the past ten years so [that] patients have a right to know information. They are demanding information; so it should have been there for the patient, without any question.

Transcript at 874. Dr. Gourley further stated that defendant also should have warned pharmacists, physicians, and family planning groups of this possibility through mailgrams or through its "detail men," as is common in the industry when studies suggest that a product might have adverse effects.[19] Transcript at 874-76.

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19 The emphatic tone of Dr. Gourley's conclusion that defendant failed to give adequate warning is evident from the following portion of his testimony:

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All in all, the Court found Dr. Gourley to be one of the most credible

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> [Y]ou can bring in a stack of studies and stack them here that says this product causes no birth defects and is not absorbed. You can bring in another stack of studies and say just the opposite here. You can line people up all day long going both directions; one is a negative study, one a positive. It [sic) doesn't negate each other. The bottom line is, as I said earlier, number one, whether it's this product or any other, I think the information should be placed on there: "Do not use in case of pregnancy." I think that's an ethical issue from my standpoint that should be on there.
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> Number two, you can truck experts back and forth all day long on either side of the subject, and you can go on ad infinitem. In this case you had experts going on one side of it. From my standpoint, the warning should be on there and, in my opinion, it doesn't hurt the product, it doesn't - and

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witnesses presented by either side. Although he had never worked with Ortho Pharmaceutical Corporation, his background and experience in the pharmaceutical community made him well-qualified to testify on customs and practices in the industry in general. He was positive in his opinion without being dogmatic. His conduct and bearing suggested a balanced, reasoned approach to answering the questions asked of him by both sides. In short, the Court found him to be a highly credible witness.

H. Dr. Dan J. Mitchell

Dr. Dan J. Mitchell was another witness presented by plaintiffs to ad-

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> it shouldn't be taken off the market, but the patient has the right to know, and so does the health care practitioner.

Transcript at 906-07.

dress the issue of failure to warn. Dr. Mitchell, whose credentials in pharmacy include a B.S., Ph.D., and post-doctoral training, is Clinical Pharmacy Coordinator and Director of Drug Information at Northside Hospital in Atlanta. He has held a variety of positions that have involved the retrieval and dissemination of information about drugs. In his present capacity as Director of Drug Information, he has developed a formal drug information service to respond daily to questions from physicians and other medical staff. Transcript at 797-806.

Dr. Mitchell testified that in providing this service, he relies extensively on information provided by the manufacturer of a drug because other sources of information often are not readily available and because "the manufacturer typically will have access to

virtually anything that has been reported." Transcript at 807. He also stated that he is familiar with drug manufacturers' customary procedures in providing information about their products. According to Dr. Mitchell, pharmaceutical firms generally furnish such information when a product is first marketed and when changes are made in labelling. Dr. Mitchell further stated that he relies on the pharmaceutical companies to provide current and accurate information about potential side effects of their products. Transcript at 808-09.

Dr. Mitchell testified that neither Ortho Pharmaceutical Corporation nor its parent, Johnson and Johnson, ever warned him of the potential teratogenic effects of the Product. After reviewing the Oechsli and Smith studies, he concluded that "[Ortho] definitely should have

provided some form of warning..., particularly to the user of the product and probably also to health professionals," such as physicians, pharmacists, and family planning workers, of the possible relationship between spermicides and birth defects. Transcript at 809-11. In his opinion, defendant should have provided this warning in 1976 after the Oechsli study became available. Transcript at 811. The absence of such a warning led Dr. Mitchell to conclude that the package insert accompanying the Product in 1980 was insufficient. Transcript at 813-14.

On cross-examination, defense counsel questioned Dr. Mitchell at length about the significance of other studies that, unlike Oechsli and Smith, found no connection between spermicides and birth defects or that failed to replicate the

findings of those two studies. Dr. Mitchell replied that these studies did not affect his opinion concerning defendant's duty to warn. Transcript at 839. In his view, even one report suggesting that a product may cause a defect cannot be readily discounted. He stated that the existence of studies disagreeing with Oechsli and Smith does not establish conclusively that those two studies have no significance. Transcript at 822.

Dr. Mitchell further testified on cross-examination that the findings of the FDA's Fertility and Maternal Health Drugs Advisory Committee (FMHDAC), which in 1983 concluded that the Product needs no additional warning, also had no effect on his opinions concerning defendant's duty to warn. He stated:

> Those people are readily swayed, I think, by other interests,

> including pharmaceutical manufacturers, other people to whom they must report and who[m] they represent. I'm not sure what the weight of one of these advisory committees should ultimately be.

Transcript at 840.

The Court found Dr. Mitchell's testimony very creditworthy on the duty to warn issue, but assigned no weight to the portions of his testimony that spilled over into the issue of causation. Dr. Mitchell's expertise in drug information qualified him to comment on whether defendant's failure to warn satisfied the standards of the industry. His demeanor, particularly under the pressure of a vigorous cross-examination, showed no evasiveness, but rather a willingness to respond in a straightforward manner and to explain his answers. In short, Dr. Mitchell fared well in the Court's assessment of his credibility.

I. Dr. John Brown

Plaintiffs presented Dr. John Brown, an economist and actuary who is an assistant professor at Georgia State University, to establish the amount of Katie Wells' lost future earnings caused by her birth defects. The parties stipulated to Dr. Brown's qualifications as an expert.

Dr. Brown testified that in calculating these lost earnings he used the most conservative "work life expectancy" that he knew - 27.91 years - which assumed that Katie Wells would have worked from age 18 to age 45 or 46. He pointed out that if it were assumed that Katie Wells would have worked until age 65, he would have added approximately twenty more years of earnings to his estimate.

Dr. Brown produced several different calculations of the net present value of Katie Wells' lost future earnings by

using different assumptions. Under the assumption that Katie Wells would have completed only high school, at a five percent discount rate and four percent inflation rate the net present value of her lost future earnings would be $320,104; at an eleven percent discount rate and a nine percent inflation rate, that figure would be $243,402. Under the assumption that Katie Wells would have completed college, at a five percent discount rate and a four percent inflation rate, the net present value of her lost future earnings would be $415,113; at an eleven percent discount rate and a nine percent inflation rate, that figure would be $308,709. These figures, according to Dr. Brown, are based on the conclusion that Katie Wells is totally disabled. If her disability were deemed less than one hundred percent, Dr. Brown

noted that these figures would be adjusted proportionately to reflect her degree of disability. Transcript at 910-27.[20]

J. Dr. George S. Braun

Defendant began its case with the testimony of Dr. George S. Braun, currently Vice-President of Technical Affairs for Johnson and Johnson, Ortho's parent corporation. After obtaining a Ph.D. in biochemistry, in 1963 Dr. Braun joined McNeil Labs, a subsidiary of Johnson and Johnson, where he eventually became executive director of research. In 1972 he moved to defendant Ortho Pharmaceutical Corporation to become a vice-president of research. He remained at Ortho until March 1980. Transcript at 999-1002.

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20 Plaintiffs also called as witnesses two present or former employees of defendant: James Dick Robins and Lynn Jackson. Because their testi-

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Dr. Braun testified that, since approximately 1950, defendant has marketed Ortho-Gynol Contraceptive Jelly in its present form. When the Product was introduced, Dr. Braun stated, it was tested for effectiveness in preventing conception. He distinguished this spermicide from others that, in the 1960's and early 1970's, had contained the active ingredient phenylmercuric acetate, which an FDA panel later declared unsafe. Transcript at 1005-08.

Most of Dr. Braun's testimony concerned his participation during the mid-1970's on an advisory committee to the FDA, the "O.T.C. Advisory Committee," which reviewed the safety, efficacy, and

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mony played no role in the Court's decision, the Court has not addressed their testimony here.

labelling of a group of over-the-counter, nonprescription products that included vaginal contraceptives. According to Dr. Braun, the Committee consisted of four or five physicians in the field of obstetrics and gynecology, one or two pharmacists, one basic scientist, one consumer representative, and Dr. Braun as industry liaison. Dr. Braun considered each member of the panel an expert in his or her field.

Dr. Braun recounted that, beginning in 1973, this panel met four or five times each year for five years and gathered all the information available concerning the safety and efficacy of various ingredients in the products that it reviewed. According to Dr. Braun, to collect information the Committee searched the available literature, advertised for information from various sources (includ-

ing NIH), held two symposia, and received information supplied by Ortho.[21] Transcript at 1008-16.

In 1978 the Committee sent its final report to the FDA, and in 1980 the report was published in the Federal Register as a proposed monograph. In Dr. Braun's words, the report classified the nonionic surfactants tested as safe, effective, and properly labelled. Transcript at 1018-19.

Dr. Braun testified that, after reviewing the studies by Oechsli and Smith, he still concluded that in 1977 the Product did not require additional warnings relating to pregnancy. According to Dr. Braun, the "overwhelming preponderance of evidence" indicates that

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21 In Dr. Braun's opinion, the Committee "left no stone unturned" and was "ruthless" in its search for information. Transcript at 1019.

spermicides are not teratogenic. He suggested that the Oechsli and Smith studies were "substantially flawed"; as an example, he explained that some patients in Oechsli's study may have used spermicides containing the unsafe ingredient phenylmercuric acetate, which is not found in the Product. In light of the "negative teratology studies and all the other data from our experience," Dr. Braun testified, "there was just no basis for a warning." Transcript at 1022-23.

Dr. Braun further explained that changes in labelling must be done carefully because adding a warning to the label might cause concern among women using that product. Consequently, according to Dr. Braun, these women might not use that particular contraceptive, even though other contraceptives might not be suitable for them. In his opin-

ion, "the risks involved in pregnancy far exceed any potential risks that may be involved in this method of contraception." Transcript at 1023-24.

On cross-examination, Dr. Braun admitted that the Harlap article, which was published in March 1980 and which referred to the unpublished 1976 Oechsli study, was available to defendant in March 1980, in time for defendant to have added a warning to the label before Mary Maihafer allegedly purchased the Product in August or September 1980. Transcript at 1041-43.

The Court did not find Dr. Braun to be a particularly credible witness in view of his interest in the outcome of the case and his lack of training as compared to many of the other witnesses.

K. Mr. Armond Welch

Defendant next presented as a witness Mr. Armond Morris Welch, a registered pharmacist who worked for the FDA from 1946 until 1980. From 1971 until 1980, Mr. Welch had been a panel administrator assigned to the O.T.C. Advisory Committee on vaginal products, the same panel on which Dr. Braun had served. According to Mr. Welch, this panel was one of many formed by the FDA to review various products. Each panel was charged with determining whether certain products were (1) "generally recognized as safe"; (2) "generally recognized as effective"; and (3) "not misbranded." Transcript at 1056-61.

Although much of Mr. Welch's testimony about the functioning of the panel paralleled Dr. Braun's account, Mr. Welch did add several pertinent de-

tails. He stated that neither the industry representative, Dr. Braun, nor the consumer representative was allowed to vote, but that the voting members of the Committee solicited their views on all issues. Transcript at 1064. Mr. Welch also described the panel's requests for information, search of the literature, two symposia, and other efforts at obtaining data on vaginal products. According to Mr. Welch, NIH was aware of the panel's proceedings and requests for information. Transcript at 1067-77.

Quoting from the Committee's report, Mr. Welch testified that this panel had attempted to evaluate the safety of ingredients found in over-the-counter vaginal products, but found that the available literature contained little information about most of the ingredients under review. Transcript at 1077-78.

According to Mr. Welch, based on the available data and the lack of "significant adverse reports," the panel concluded that the non-ionic surfactants used in spermicides were safe for over-the-counter use. Transcript at 1078. In Mr. Welch's opinion, despite the panel's concern about the scarcity of available information, the panel members felt they had sufficient information to reach this conclusion. Transcript at 1083. Moreover, Mr. Welch could recall no suggestion by the panel that spermicides containing non-ionic surfactants should carry a warning concerning teratogenicity or pregancy. Transcript at 1085-86.

Mr. Welch added that other products containing non-ionic surfacant spermicides have since undergone the scrutiny and testing of the FDA's "New Drug Application" procedure. At least two of these

products - a vaginal sponge and a lubricated condom using non-ionic surfactants - have been approved by the FDA without any warning concerning teratogenicity or pregnancy. Transcript at 1087-89.

On cross-examination, Mr. Welch testified that at one time "there was a rumor of a report" at NIH that might have been relevant to the Committee's inquiry. He was assigned to obtain a copy of this report for the panel. According to Mr. Welch, upon inquiring about the report, he was informed that whatever the report was, it would not be available during the life of the panel. Transcript at 1103-08.

Generally, Mr. Welch was an honest but unimpressive witness. His training was not extensive, nor did his testimony as to the panel's investigation greatly assist the Court in its findings.

L. Dr. Richard N. Watkins

Dr. Richard N. Watkins next testified for defendant. Dr. Watkins, a physician who is board-certified in emergency medicine, practices in Seattle with Group Health Cooperative of Puget Sound. He testified that he has participated in several epidemiological studies and was a co-author of the 1981 Jick study, "Vaginal Spermicides and Congenital Disorders."

Dr. Watkins' testimony focused on how his study had been conducted and on his criticisms of the study. He stated that he had helped obtain approval to use the records of Group Health Cooperative as a data source for the proposed study, had assisted in the collection of the data, and had reviewed between four and eight drafts of the study prior to publication. Transcript at 1118-28.

Dr. Watkins explained that the study defined persons as "presumed exposed" to spermicide if the mother had received a prescription for spermicide within eleven months before conception. Dr. Watkins then summarized the study's findings of major congenital anomalies. Of the total population, four infants had limb reduction defects, and three of these were presumed exposed. Two infants with neoplasms were presumed exposed. Three of four infants with chromosomal anomalies were presumed exposed, as were two infants with hypospadias.[22] Dr. Watkins further observed that the study

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22 The article summarized its findings as follows: "Among 763 liveborn infants of white women who had obtained a vaginal spermicide in the ten months before conception, the prevalence of certain major congenital anomalies was 2.2%. The prevalence of such a comparison group of 3,902 infants was 1.0%." Jick, supra note 12, at 1329.

found no cleft lips, amniotic banding, or eye anomalies among those infants presumed exposed. Transcript at 1124-27.

On direct examination, Dr. Watkins testified that the first draft of the study had made him "rather ill at ease" because "there were several problems." Transcript at 1128. The first, he stated, was the question whether mothers in the "presumed exposed" group actually had used spermicide. Second, he testified that the size of the population was too small. Third, he had reservations that "these disparate conditions were lumped together without assigning causality." Transcript at 1128-29. Dr. Watkins testified that he voiced his objectons to Dr. Jick and to members of Group Health's medical staff; he recalled that the staff reacted negatively to the study after reviewing it. Subsequently, according to

Dr. Watkins, Dr. Jick requested that Dr. Watkins have nothing more to do with the study. Transcript at 1129-34.

Dr. Watkins went on to testify that sometime after the study was published, at the request of an employee of defendant he reviewed more closely the records of some of the patients in the study.[23] He stated that, in his opinion, some mothers identified in the study as users of spermicide in fact were not using spermicide. Transcript at 1135-36, 1153. Dr. Watkins concluded that he did "not believe that any reasonable conclusion regarding the association of the use of the spermicides with congenital defects

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23 Defendant did not make these records available to opposing counsel or to the Court. Transcript at 1138-43.

can be drawn" from this study. Transcript at 1156.

On cross-examination Dr. Watkins acknowledged that, despite his present criticism of the Jick study, he had been a co-author and had signed his name to the Jick study before it was published in the widely-read Journal of the American Medical Association. Transcript at 1161-62. Dr. Watkins admitted that prior to signing as co-author of the study, he had learned of one instance in which a nurse had discovered that one mother identified by the study as a user of spermicide actually had planned her pregnancy; nonetheless, he signed as co-author. Transcript at 1168. He further admitted that, except for that single instance, he had no other information about "presumed users" being "non-users" until one or two months before trial, when he investigated

the data underlying the study at defendant Ortho's request. Transcript at 1169. Moreover, Dr. Watkins conceded that although he previously had indicated to certain individuals his concerns about the study's conclusions, in the almost four years since the study was published he had never before stated these concerns publicly. Transcript at 1170. Finally, Dr. Watkins testified that he was not familiar with the studies by Oechsli, Smith, and Buttar that addressed the potentially harmful effects of spermicides on developing fetuses. Transcript at 1170-71.

Because he had participated in the 1981 Jick study, Dr. Watkins might have been an ideal witness to comment on the validity of its conclusions. Dr. Watkins' testimony on cross-examination, however, severely eroded his credibility.

It is perplexing that a physician would risk his professional reputation by signing his name to a study about which he had serious reservations, especially when he knew the article would be published in a widely-read journal. See Transcript at 1128-35, 1161. Moreover, the dispute between Doctors Jick and Watkins, when Dr. Jick requested that Dr. Watkins discontinue work on the study, creates some question about Dr. Watkins' impartiality. Finally, that Dr. Watkins chose this courtroom as the first public forum in which to repudiate a study that he had helped conduct nearly four years earlier creates further doubt about his credibility. For those reasons, the Court found Dr. Watkins' testimony not credible.

M. Mr. Robert M. Kirsch

Defendant also presented as a witness Mr. Robert M. Kirsch, who for the

past twelve years has worked for Johnson and Johnson or one of its affiliates. For the past five years, Mr. Kirsch has been in the employ of defendant Ortho Pharmaceutical Corporation, where he presently is Manager of Regulatory Affairs, Advanced Care Products Division. Mr. Kirsch stated that he holds a bachelor's degree in biology and that his only postgraduate training has been in business. Transcript at 1186-87.

Mr. Kirsch testified that his duties with defendant include ensuring that his division complies with federal law and managing his division's preclinical toxicology testing. He noted that defendant has sold millions of tubes of Ortho products containing non-ionic surfactants, including but not limited to Ortho-Gynol Contraceptive Jelly. Mr. Kirsch observed that Ortho-Gynol Contra-

ceptive Jelly was on the market before the institution of the FDA's "New Drug Application" procedures, which require that drugs be tested in animals and humans for safety and effectiveness. Nonetheless, he stated that other Ortho products containing the same or similar non-ionic surfactants have been approved by the FDA under these procedures. Transcript at 1181-91.

Mr. Kirsch's area of responsibility at Ortho is animal testing, and he discussed various tests sponsored by Ortho or by other groups investigating the effects of non-ionic surfactants. According to Mr. Kirsch, these tests, which are described more fully in the footnote below,[24] attempted to measure

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24 According to Mr. Kirsch, beginning in 1969 Ortho conducted several

(footnote continued on next page)

irritation; toxicity, including carcinogenicity and mutagenicity (i.e., effects

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tests to measure irritation caused by the product in rats and rabbits. These studies showed mild to moderate irritation in the animals tested. Mr. Kirsch stated that although these tests are not "directly extrapolatable to humans," they are indicators of the Product's effect on humans. Transcript at 1194-96.

Mr. Kirsch also mentioned toxicity tests using dogs and rats; these tests noted no adverse effects. Transcript at 1197-98. He discussed a study that was conducted in 1978 by a toxicologist employed by Ortho: Arbrutyn, Teratology Study of Intravaginally Administered Nonoxynol-9 Containing Contraceptive Cream in Rats, 37 Fertility and Sterility 113 (1982). According to Mr. Kirsch, this study indicated no teratological effects associated with the Product. Transcript at 1200. Next, Mr. Kirsch mentioned a rat study commissioned by Ortho that noted no carcinogenic or systemic toxic effects after two years of administration. Transcript at 1201. Additionally, Mr. Kirsch mentioned a chronic toxicity study that attempted

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on genes and chromosomes); and teratogenicity. Although these tests showed that non-ionic surfactants cause mild to moderate irritation in animals, according to Mr. Kirsch they indicated no toxic or teratogenic effects. Transcript at 1194-1206.

Mr. Kirsch testified that he knew of no animal testing that has found a non--ionic surfactant to be a teratogen.

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to measure systemic safety and the 1981 Ames mutogenicity test on octoxynol-9 and nonoxynol-9, which attempted to measure the effects on chromosomes and genes. Transcript at 1202-04. Finally, Mr. Kirsch explained another Ortho study: Sodd, Teratology of Intravaginally-Administered Contraceptive Jelly Containing Nonoxynol-9 in Rats, Teratology Magazine (1984). According to Mr. Kirsch, this study noted no teratological, embryolethal, or fetocidal effects in rats whose mothers had received various doses of the spermicide in days six through fifteen of the twenty-one-day gestation period. Transcript at 1204-06.

When asked if he knew of any studies that indicated that non-ionic surfactants are not teratogens, he mentioned that he had seen abstracts of the Buttar study of embryotoxicity and teratogenicity, which found "no discernible skeletal malformations." Still, Mr. Kirsch conceded that he had "very little information on the study itself," "was not familiar with its methodology," and that therefore it was "difficult for me to assess his results." Transcript at 1206-09.

Mr. Kirsch criticized procedures used in the Chvapil study, which indicated that nonoxynol-9 is absorbed through the vagina. He testified that Ortho had conducted a study that could detect no absorption of nonoxynol-9 thorugh the vagina. Transcript at 1212-14.

The testimony of Mr. Kirsch also touched on several aspects of the government's activities in this area. Mr. Kirsch remarked that studies on the spermicide continued at Ortho even after 1980, when the O.T.C. Advisory Committee's report deemed the Product safe and effective. He further testified that in August 1983, the FDA exempted vaginal contraceptive products from a "pregnancy warning" because they were "not intended for systemic absorption." Transcript at 1215-17. Finally, he stated that Ortho had no control over selection of committee members of the FMHDAC, which discussed the relationship between spermicides and birth defects, but that Ortho was invited to suggest possible speakers to appear before the Committee at its December 1983 meeting. Transcript at 1219.

On cross-examination, Mr. Kirsch agreed that even though one of the Buttar studies found "no discernible skeletal malformations," the study did conclude that the spermicide was embryolethal and fetocidal. Transcript at 1435-36. He also agreed that a significant difference between this study and the one performed by his division at Ortho was that the latter did not introduce spermicide until day six of gestation, while the former applied it at day one. Transcript at 1436.

In assessing the credibility and persuasiveness of Mr. Kirsch's testimony, the Court was not impressed by his background. Although he testified at length about the findings of various scientific studies, his educational background in science is limited to an undergraduate degree. Moreover, his credibility suf-

fered because at times the scope of his opinion exceeded the scope of his knowledge; for example, he readily offered his conclusion about the Buttar study of embryotoxicity and teratogenicity, despite his admitted lack of familiarity with that study.[25] See Transcript at 1206-09. Of course, that Johnson and Johnson or one of its affiliates has been Mr. Kirsch's employer for the past twelve years added nothing to his believability. Taking into account these factors and the witness' overall tone and demeanor at trial, the Court did not assign much weight to his testimony concerning the critical issues in this case.

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25 The Court recalls Dr. Holbrook's and Dr. Buehler's contrary interpretations of this Buttar study and points out that reasonable minds dispute Mr. Kirsch's opinion of what conclusions should be drawn from it.

N. Dr. Paul Stolley

The next expert witness to testify for defendant was Dr. Paul David Stolley, a professor of medicine and co-director of the Clinical Epidemiology Unit at the University of Pennsylvania. Dr. Stolley's background and credentials were most impressive: he has had extensive experience in epidemiology, has served on several advisory committees to the FDA, has received numerous honors and awards, and has published 105 articles, most in the field of epidemiology. Further, he is board-certified in internal medicine and public health and is a reviewer or editor of several journals. Transcript at 1228-37.

After providing a background of epidemiological terms and principles, Dr. Stolley addressed from an epidemiologist's viewpoint the various studies that

have considered whether spermicides may cause birth defects. First, he discussed the Oecshli study, which according to Dr. Stolley "raised some small suspicion about a possibility of an association of spermicides with severe malformations." Transcript at 1270. Dr. Stolley criticized the Oechsli study because, in his opinion, the suggested association with birth defects was not strong, the study failed to specify whether any of the spermicides in question contained phenylmercuric acetate instead of non-ionic surfactants, and the results of the study were not duplicated in certain other groups of diaphragm users. Further, Dr. Stolley noted the study's suggestion that its findings "may have been a statistical fluke," although he also mentioned that the study concluded that "[f]urther re-

search is stongly indicated." Transcript at 1269-75.

Dr. Stolley contrasted the Oechsli study with several others that have suggested no association of non-ionic surfactants with birth defects. The 1980 Harlap article and one unpublished study by Harlap,[26] which according to Dr. Stolley had a greater ability to detect a true risk than the Oechsli study, could not replicate Oechsli's findings. A similar result in the Mill's study[27] suggested to Dr. Stolley that Oechsli's

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26 Harlap, Congenital Abnormalities in the Offspring of Women Who Used Oral and Other Contraceptives around the Time of Conception (unpublished study). This study was supported by the Center for Population Research, National Institute of Child Health and Development.

27 Mills, Are Spermicides Teratogenic?, Journal of the American Medical Association, Nov. 5, 1982, at 2148.

findings were a "statistical fluke." Transcript at 1276-92.

Dr. Stolley also questioned what conclusions could be drawn from the Smith study, on which plaintiffs also relied. In Dr. Stolley's view, the apparent association of limb defects and spermicide use noted in this study could have occurred by chance alone and was "not striking." Additionally, the doctor noted that Smith's data had been gathered at a time when some spermicides contained phenylmercuric acetate. Dr. Stolley stated that he concluded from Smith "that spermicides are not related to limb reduction defects." Transcript at 1294-1301. He also testified that the completed Warburton study could not confirm the Warburton abstract's previous suggestion that certain chromosome anomalies

are related to spermicides. Transcript at 1302-04.

In Dr. Stolley's opinion, the 1981 Jick study was the first published study to associate limb reduction defects with spermicide use. Transcript at 1318. Still, he rejected Jick's findings. According to Dr. Stolley, Jick had so loosely defined "exposure" to spermicides that his data was "almost uninterpretable." Transcript at 1312. Among Dr. Stolley's other criticims of the Jick study were that the diversity of birth defects was "biologically implausible," that a low percentage of malformations in the control group may have artificially inflated the results, and that the size of the study was too small. If, as Dr. Watkins had suggested, two of three "presumed users" of spermicide in the Jick study were not users, according to Dr.

Stolley the study would show no association between spermicides and limb reduction defects. Even without that assumption, in Dr. Stolley's opinion, Jick's failure to confirm exposure to spermicides made the study "so vague as to be meaningless." Transcript at 1321-22. According to Dr. Stolley, no other studies have replicated Jick's results, and in fact several other studies have detected no association between spermicides and birth defects. Transcript at 1304-11, 1347-43.

Based on his review of the transcript of the December 1983 meeting of the FMHDAC, Dr. Stolley testified that, in his opinion, the Committee's discussion of spermicides and congenital abnormalities was comprehensive and thoughtful. Further, he felt that the Committee was not unduly influenced or

biased by defendant Ortho Pharmaceutical Corporation. Transcript at 1345.

Finally, Dr. Stolley stated his conclusion that spermicides have been "well-studied" and have been shown "clearly" not to cause congenital anomalies, specifically limb reduction defects. Transcript at 1346. He stated that in his opinion the Product required no warning teratogenicity in 1980. In fact, Dr. Stolley testified that such a warning would have been "irresponsible." In his view, a proliferation of warnings causes consumers to disregard them, particularly when new data later show no warning was necessary. Because he felt that the Product was safe, Dr. Stolley observed that a warning might do more harm than good by prompting some women to use other forms of contraception not appropriate for them or to stop using

contraceptives entirely. Transcript at 1346-50.

On cross-examination, Dr. Stolley disagreed with suggestions made by plaintiffs' experts that spermicides might cause an unpredictable variety of birth defects, such as the variety described in the Jick study. Transcript at 1369. Dr. Stolley acknowledged that his characterization of the Oechsli study as raising "some small suspicion" of an association between spermicides and malformations was inconsistent with Oechsli's own conclusion that the study raised a "serious suspicion." Transcript at 1373 (emphasis added).

Also on cross-examination, Dr. Stolley addressed what conclusions could properly be drawn from the Shapiro

study[28] which Dr. Stolley described as a "very good study" and on which he relied "heavily" in formulating his opinion that spermicides have been "shown clearly not to cause" birth defects. Transcript at 1346, 1406-07. Specifically, plaintiffs' counsel questioned Dr. Stolley about the following statements made at the 1983 FMHDAC meeting by Dr. Shapiro:

> There is one question that is unanswered and that we fully

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28 Shapiro, Birth Defects and Vaginal Spermicides, Journal of the American Medical Association, May 7, 1982, at 2381. The Shapiro study concluded as follows:

> We conclude that there is no satisfactory evidence to indicate that spermicides increase the overall risk of major birth defects. It is possible, however, that spermicides increase the risk of certain malformations. Our own study is not large enough to exclude such a possibility. To evaluate it, further studies are needed.

Id. at 2384.

> acknowledge, and that is that all of the cohort studies so far done, or the case control studies, for that matter, lack the power to evaluate in statistical terms that there is not an appreciable increase in the risk of specific birth defects.
>
> ....
>
> I'm not for one moment claiming that this study rules out an increase in the risk of limb reduction deformities.

Transcript at 1408-10. Dr. Stolley disagreed with Shapiro that available studies could not rule out an "appreciable increase" in risk. He continued as follows:

> I think that what [Shapiro] is saying is that, if there were a tiny increase in limb reduction defects, which is rare, you would need an extremely large study to absolutely rule that out and <u>that can't be done</u>.
>
> ....
>
> What he was trying to do is address the question of ruling out very, very tiny risks, and I think that I

> would agree that it's very difficult to do that.
>
> ....
>
> I think to me the data is quite conclusive in that it does not demonstrate - does not demonstrate an association of spermicides with limb reduction defects or with any other congenital anomaly.
>
> ....
>
> I think that Doctor Shapiro would agree with my statement, and that it is that no association between spermicides and birth defects has been shown, and I agree with him when he says a small increase cannot be ruled out. I think that's true about a small increase in anything, but why should one even bother to do that given data that doesn't show any substantial association as it now stands.

Transcript at 1411-13 (emphasis added).

The Court found Dr. Stolley's credentials to be impressive and his testimony concerning the various studies to be helpful and informative. Several aspects of his testimony, however, led the Court to assign little weight to Dr. Stolley's opinions about the ultimate issues in

this case. Dr. Stolley's responses on cross-examination and his overall demeanor and manner indicated a degree of bias. The Court also was struck by the difference between his apparent certainty on direct examination and his less-than-certain tone on cross. Several times during direct examination, Dr. Stolley testified emphatically that a specific study or studies showed that spermicides are not related to birth defects. See, e.g., Transcript at 1301. In the portions of his testimony on cross-examination quoted above, however, Dr. Stolley equivocated. His interpretation of the studies discussed was that "no association between spermicides and birth defects has been shown," but on cross he conceded that "a small increase [in birth defects] cannot be ruled out." Finally, by disagreeing with Shapiro's warning

that an "appreciable increase" cannot be ruled out, Dr. Stolley in effect was expressing greater confidence in Shapiro's findings that Shapiro himself thought was justified. Transcript at 1413. In short, because of his apparent bias and his overstatements, the Court discounted Dr. Stolley's conclusions.

The above passages from Dr. Stolley's testimony are significnt because they help define the Court's role as factfinder in this case. Although these scientific studies are invaluable aids, Dr. Stolley's testimony demonstrates that the studies alone do not show conclusively whether or not Katie Well's birth defects were caused by Ortho-Gynol Contraceptive Jelly. Further, the Court reiterates that plaintiffs' ultimate burden was not to produce a flawless epidemiological study, but

rather to show from all the evidence presented, to a reasonable degree of medical certainty, that the Product caused some or all of Katie Well's birth defects in 1980.

O. Dr. Bohdan Malyk

Defendant next presented as a witness its Director of Medical Affairs and Clinical Research, Dr. Bohdan Malyk, who sat at defense counsel's table throughout most of the trial. Dr. Malyk is a physician who specializes in obstetrics and gynecology, who is board-certified in that field, and who has served on the faculties of several medical schools. He has held his present position with Ortho for five of the nine years that he has worked for Ortho. He testified that his responsibilities with Ortho include the following: conducting all clinical studies for Ortho's Advanced

Care Products Division, which manufactures and markets contraceptives; reviewing the available literature; reviewing the labelling of products; answering questions from health professionals and consumers; and generally setting policy for the medical research department. Transcript at 1445-50.

Dr. Malyk testified that Ortho has an "extensive capability" for keeping up with the current scientific literature. Much of his testimony concerned his comments about the various studies of the effects of spermicides. Dr. Malyk stated that he had become aware of the Oecshli study only after this lawsuit was filed.

He remembered reading the Harlap article shortly after it was published in 1980 and recalled being reassured that Harlap's findings did not replicate those

mentioned in the citation to Oechsli. Based on his recent review of the Oechsli study, Dr. Malyk rejected Oechsli's conclusions. In Dr. Malyk's opinion, the population studied by Oechsli likely included many "high-risk" patients, making the study "essentially invalid." He testified that he did not believe that Ortho would have acted differently even if the Oechsli study had been delivered to Ortho in 1976 or 1977. Transcript at 1451-55.

Next, Dr. Malyk stated that although he had probably read the Smith study in 1977, he did not recall reading it then. From his later review of the study, he concluded that the study was "not striking" because its authors essentially reported a negative finding. Further, Dr. Malyk suggested that because the study was Canadian, the spermicides

involved may have contained active ingredients approved for use in Canada but not in the United States. According to Dr. Malyk, Ortho was correct in not changing its marketing of the Product after the Smith article was published. Transcript at 1455-57.

Dr. Malyk also commented on the Warburton abstract. He noted that the abstract was only a preliminary report of an ongoing study, and he testified that the authors' later findings did not confirm their earlier ones. Further, he pointed out that the birth defects examined in the Warburton study were different from those suffered by Katie Wells. Transcript at 1457-61.

Dr. Malyk next took issue with the studies suggesting vaginal absorption of non-ionic surfactants. According to Dr. Malyk, before these studies were pub-

lished, his division at Ortho had begun its own study of absorption. He criticized the methodology of the Chvapil study and stated that the study's indication that nonoxynol-9 is vaginally absorbed had not "concerned" him because he knew the methodology was not good. He also rejected the Buttar absorption study because it employed a similar methodology.[29]

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29 Dr. Malyk also briefly addressed the second Buttar study, which considered the embryotoxic and teratogenic effects of non-ionic surfactants in animals. For purposes of assessing Dr. Malyk's credibility, this passage is worth reproducing here to illustrate the terse and conclusory tone that often characterized his testimony:

(On direct examination:)

Q. Then let's go to plaintiffs' exhibit 38, which is the other - which is the Buttar abstract. That study does reference teratogenicity, does it not?

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According to Dr. Malyk, to his knowledge the only study addressing

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A. Yes, I believe it does.

Q. Other than the Ortho tests, are you aware of any other animal tests which have related to teratogenicity of a spermicide?

A. I'm sorry, would you repeat that question?

Q. Other than the tests Ortho has done -

A. Unh hunh.

Q. - are you aware of any animal tests that have dealt with teratogenicity of a non-ionic surfactant other than Buttar, that particular exhibit?

A. No, I'm not.

Q. What did Ortho's test show about teratogenicity?

A. That it was non-teratogenic.

Q. What does Buttar say about it?

A. It's non-teratogenic.

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vaginal absorption of these ingredients was Ortho's own study, the preliminary report of which was published in June 1981.[30] Ortho's study detected no vaginal absorption of these non-ionic surfactants. Transcript at 1461-80.

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> Q. Therefore, is there any animal test that you are aware of that indicates that a non-ionic surfactant is a teratogen?
>
> A. None that I'm aware of.
>
> Transcript at 1472. This cursory discussion of the second Buttar study ignores the author's findings that non-ionic surfactants may be embryolethal and fetocidal in rats, a conclusion that according to Dr Buehler and Dr. Holbrook indicates that non-ionic surfactants may be teratogenic in humans. See supra notes 13, 18, and accompanying text.

30 Malyk, Preliminary Results: Serum Chemistry Values Before and After the Intravaginal Administration of 5% Nonoxynol-9 Cream, 35 Fertility and Sterility 647 (1981).

Dr. Malyk also discussed various aspects of the testing and labelling of products at Ortho. He acknowledged that a warning concerning pregnancy and teratogenicity could "chill" sales of the Product, but rejected the suggestion that the lack of such a warning was financially motivated. Transcript at 1480-93.

Another matter addressed by Dr. Malyk was Mary Maihafer's use of the spermicide. He testified that a sample tube contains three applications; a tube the size Mary Maihafer allegedly purchased contains eleven to twelve applications; and an even larger tube contains eighteen to nineteen applications. He statd that he had attempted to apply the spermicide in the same manner as Mary Maihafer had demonstrated in court and had concluded that, based on the amount

she stated that she had purchased, at most she would have had eighteen applications. Transcript at 1495-99.

In assessing Dr. Malyk's credibility, the Court first considered his background. Dr. Malyk stated that he had no formal specialized training beyond his medical degree. Moreover, he is an employee of the defendant in this case. In his testimony Dr. Malyk often was quick to offer terse, conclusory opinions that were favorable to defendant, as illustrated by his comments on both Buttar papers.[31] Based on the potential

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31 In addition to the testimony excerpted in notes 29, an earlier passage illustrates the tone of Dr. Malyk's testimony:

> [Dr. Buttar] was subject, really, to the same shortcomings that Doctor - the same errors, unfortunately, that Dr. Chvapil made in that the material that he was using from New

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bias of this employee and based on his bearing and manner at trial, the Court concluded that Dr. Malyk was not a convincing witness.

P. Dr. Robert L. Brent

Defendant's final and primary expert witness was Dr. Robert L. Brent. Dr. Brent is a pediatrician, embryologist, and teratologist who has a Ph.D. is enbryology and rediation biology and an M.D. Dr. Brent has had very extensive experience in teaching, research, and

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> England Nuclear, although he says that it's 97 percent pure in his paper, on one of the pages, I forget what page, that was really an error on his part, and, again the validity of his conclusions are really suspect.
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> Transcript at 1469-70. When Dr. Malyk rejects without explanation Buttar's statement that certain material is 97 percent pure, the Court must conclude that it is the validity of Dr. Malyk's conclusions that are "really suspect."

writing. He is a full professor of pediatrics, radiology, and anatomy at Thomas Jefferson University in Philadelphia and serves as director of both the Cancer Research Institute and the Stein Research Center. He has received numerous honors and awards, and his 326 publications include many articles relating to teratology.[32]

Dr. Brent testified that major birth defects occur in approximately three percent of all live births. According to Dr. Brent, the causes of sixty to sixty-five percent of these defects are unknown, and genetic causes account for

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32 Dr. Brent also is a charter member, founder, and past president of the Teratology Society. He has served on the editorial boards of several journals and presently is editor-in-chief of Teratology - Study of Abnormal Development. He also has worked as a consultant with the FDA and NIH. Transcript at 1550-68.

another twenty to twenty-five percent of major birth defects. He stated that approximately ten percent of major defects are attributable to environmental factors, a category that includes drugs and chemicals. Transcript at 1568-81.

Dr. Brent described the first two weeks of human development as the "all or none" period. He testified that if a human embryo is injured before the 16th or 17th day after conception, according to the "all or none" principle it will either die or survive and be normal. Dr. Brent characterized this principle as not simply his opinion, but as a basic concept in embryology.[33] Transcript at 1589-91. Moreover, according to Dr.

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33 In Dr. Brent's words, the chart on which he relied in explaining this concept "doesn't say if they survive they will be normal, but that happens to be true." Transcript at 1591.

Brent's explanation of the development of limbs and hands, the available evidence indicates that defects in limb development are not caused by exposure to a teratogen before the 24th day, when limb development begins. Further, he testified, damage to a developing hand would not occur before the 35th day. Transcript at 1594.

Based on his review of medical records and photographs of Katie Wells,[34] Dr. Brent testified that, in his opinion, none of her malformations were caused by a non-ionic surfactant. He rejected the suggestion made by some of plaintiffs' experts that a sperm damaged by spermicide could still fertilize an egg. He also stated that while, theoretically,

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34 The Court found it significant that neither Dr. Brent nor any other of defendant's experts had ever examined Katie Wells.

an egg or zygote could be killed by spermicide carried by a sperm, no limb reduction defects would result if the egg or zygote survived. Transcript at 1000-04.

Addressing the absorption studies, Dr. Brent pointed out that the Buttar study and the Ortho study conducted by Dr. Malyk showed that very little, if any, of the Product could be absorbed and reach the fetus. Transcript at 1607-09, 1618, 1624. Dr. Brent suggested that no teratogenic or embryotoxic effects can result at such low levels of concentration. Transcript at 1609, 1618-19.

The doctor characterized the other Buttar study as a poor one to measure teratogenicity. He dismissed the suggestion that Buttar's finding that non-ionic surfactants are embryolethal and fetocidal in rats might indicate that

they are teratogenic in humans. Because Buttar exposed embryos to spermicides from the earliest stages of development, according to Dr. Brent the embryolethality Buttar observed was attributable not to teratogenesis, but to the "all or none" phenomenon. Transcript at 1615. Dr. Brent was not surprised that Buttar had found no skeletal malformations because Buttar had exposed the embryos too early, in Dr. Brent's opinion. Transcript at 1616-17.

Dr. Brent testified that if, on the 26th or 27th day, a mother stopped using an agent capable of producing limb defects, it was "unlikely" that the agent would have produced the type of limb defect suffered by Katie Wells. Transcript at 1621. In Dr. Brent's opinion, Katie Wells' shoulder and hand

deformities and cleft lip most likely[35] were caused by the amniotic band syndrome, which the literature has never associated with non-ionic surfactants.[36] Transcript at 1628-30. Taking issue with Dr. Buehler's conclusion, Dr. Brent did not believe the smoothness of Katie Wells' shoulder and her underdeveloped clavicle and scapula were the result of a vascular problem. Transcript at 1635, 1638-42.

When asked how a teratologist proves or disproves teratogenicity, Dr. Brent stated that he considers whether the allegation of teratogenicity is consist-

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35 Other less likely possibilities suggested by Dr. Brent were that the defects were caused by a diabetic pregnancy or by some constraint in the uterus. Transcript at 1630-32.

36 Dr. Brent stated that the causes of the amniotic band syndrome have not been found. Transcript at 1652.

ent with epidemiological studies, animal studies, and basic science concepts. In Dr. Brent's opinion, none of these three indicators suggests that non-ionic surfactants are teratogenic. Other than the Jick study, he was aware of no studies showing a statistically significant association between spermicides and birth defects. As he criticized the Jick study, he observed that it is not surprising for an occasional study to suggest an association, but that the "mass of data" must be considered. Transcript at 1643-52. Further, he commented on the limits of these scientific tests:

> [T]here's no way to prove that a substance is not teratogenic. It's proving a negative, and, in fact, it's true of water and vitamins and everything else that we are exposed to. All we can say is that after extensive evaluation, the risk appears no greater than if you didn't expose yourself to that. That's about as far as you can go.

Transcript at 1653-54.

Dr. Brent also discussed his involvement in this litigation, which preceded and resumed after his participation in the December 1983 FMHDAC meeting. In June 1983, according to Dr. Brent, he first met with defense counsel in this case to discuss the allegations about spermicides and birth defects. Transcript at 1654. Dr. Brent testified that he learned from defense counsel in the fall of 1983 that the FMHDAC was to discuss this issue. Because Dr. Brent was to participate as a voting member of that committee, defense counsel advised him then that he would not participate further in evaluating this case until after the FMHDAC's hearing. On direct examination, Dr. Brent testified that he was not "retained" by defendant until March 1984. Transcript at 1655-56.

The FMHDAC, Dr. Brent explained, is a standing committee that meets two to three times yearly to discuss matters chosen by the FDA. Dr. Brent testified that at the December 1983 meeting, the Committee heard oral presentations by Doctors Jick, Harlap, Shapiro, and others and discussed the Oechsli study. According to Dr. Brent, the Committee members unanimously felt that they could not "demonstrate an increased risk or association of the alleged malformations with exposures to spermicide and that no change in the product labelling should be suggested." Transcript at 1600.

In Dr. Brent's opinion, an additional warning on the Product would "miseducate" the public. The result of a warning would be, in Dr. Brent's words, a "potential major tragedy" because a warning would cause some patients to stop

using the Product when the benefits to them from using it actually outweigh the risks. Transcript at 1660-63.

On cross-examination, plaintiff's counsel elicited several items of information from Dr. Brent that placed his credibility in question. First, Dr. Brent had initially testified that he was first "retained" by Ortho in March 1984. He later revised this date as February 10, 1984. Defendant, however, described Dr. Brent's expected testimony in interrogatory responses that were served on February 9, 1984, and that obviously must have been prepared some time prior to the date served. Transcript at 1673-74, 1702-03. Second, although Dr. Brent had discussed the allegations in this case with defense counsel in June 1983, Dr. Brent did not inform the Committee that he had previously been

contacted by Ortho about this case. Transcript at 1678.

Most interesting was Dr. Brent's past active involvement in litigation concerning contraceptives. Dr. Brent acknowledged that he had reviewed depositions and transcripts from almost 200 lawsuits concerning birth defects. Based on this review, he published an article in which he alleged that over fifty percent of plaintiffs' expert witnesses distorted the truth, while less than ten percent of defendants' experts had done so. Transcript at 1681-82. In another article, entitled "Lawyer-Produced Pain & Suffering," Dr. Brent had written the following:

> The case histories clearly indicate that when a family becomes orchestrated by a lawyer into the position of devoting a great deal of their energy to litigation, many of the priority family responsibilities are ignored and important critical standards are distorted. To win at

> all costs may be good for football teams, but it is obviously bad for a family.

Transcript at 1684-85.

When Dr. Brent attempted to explain an article in which he had criticized expert witnesses who "act as partisans rather than as scholars," the Court asked his whether he believed that the other qualified experts in this case whose opinions were inconsistent with his were necessarily advocates for the plaintiff, or whether he acknowledged that there could be honest differences of opinions concerning what caused Katie Wells' birth defects. Dr. Brent say no possibility of "honest differences of opinion" in this case.[37] Transcript at 1685-88.

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37 The following passage illustrates Dr. Brent's viewpoint:

(footnote continued on next page)

On re-direct examination, Dr. Brent testified that although he had read Dr.

(footnote continued from previous page)

> THE COURT...[I]f you have a situation where a doctor testifies on behalf of the plaintiff with the same or equal background that you have, why is it necessarily true that you are right and he's wrong?
>
> [DR. BRENT]: Well, obviously, I don't think that I am wrong.
>
> THE COURT: I understand you don't think you are wrong. You have stated very positively that spermicides in this case did not cause this child's defects.
>
> [DR. BRENT]: To the best of our scientific ability to make a determination of the allegation of the teratogenicity, the data doesn't support the allegation.
>
> THE COURT: And, yet, we have testimony on behalf of the plaintiff to the contrary from doctors who are eminently qualified. Now, how would you explain that?

(footnote continued on next page)

Buehler's deposition, he was not aware of what Dr. Buehler had relied on in forming his conclusions, nor of any matters that Dr. Buehler did not consider. Transcript at 1700.

The Court found that although Dr. Brent's credentials were most impressive, he was not a convincing or credible witness. His criticisms of plaintiffs' attorneys and of expert witnesses who testify for plaintiffs in malformation lawsuits strongly suggest a distinct prejudice against plaintiffs and a corresponding bias in favor of defendants in such cases. He assisted in defense counsel's preparation for this case in June 1983, and yet later participated in

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[DR. BRENT]: They are wrong. Transcript at 1688.

the FMHDAC's investigation of closely related questions without disclosing his prior activities in this case. In the Court's view, Dr. Brent's association with Ortho before and after the December 1983 Committee meeting created serious doubts not only about Dr. Brent's credibility and objectivity in this trial but also about the weight this Court should attribute to the Committee's findings.

The exaggeration by Dr. Brent and the absolute terms in which he expressed his conclusions also detracted from his believability. Although at times he acknowledged that there is an inherent lack of certainty in determining the cause of birth defects, more often Dr. Brent's testimony and manner suggested a degree of conviction in his own conclusions unwarranted in a discipline

in which, according to other competent experts from both sides, explanations are only more or less probable. For these reasons, Dr. Brent lacked credibility as a witness.

FINDINGS OF FACT

At the close of all the evidence, the Court granted defendant's motions to dismiss several of plaintiffs' claims because the evidence presented by plaintiffs simply could not support them. First, the Court dismissed the claim for breach of warranty because plaintiffs had not shown the privity of contract required by Georgia law. See Watkins v. Barber-Colman Co., 625 F.2d 714, 716 (5th Cir. Unit B 1980) (applying Georgia law). Second, the Court found no evidence of negligence per se and dismissed that claim. Third, the Court dismissed the

claim for negligent failure to warn that the product does not always prevent conception. The uncontradicted evidence at trial showed that the Product did carry such a warning, that Ms. Maihafer read the warning before beginning to use the Product, and that she knew that the Product is not one hundred percent effective. Fourth and fifth, the Court dismissed for lack of evidence the claims alleging fraud and "conspiracy." Sixth, the Court found no evidence of an intentional tort by defendant and dismissed that claim also. Last, the Court concluded that plaintiffs had not shown that defendant's failure to warn was attributable to a "conscious marketing decision" and, therefore, that the facts developed by plaintiffs at trial would not support a claim for punitive damages. Transcript at 1717-19.

Reviewing the evidence that was relevant to plaintiffs' remaining claims, the Court made its factual findings. First, the Court found that plaintiff Mary Maihafer had properly used the Product according to the instructions every time that she and Gary Wells had sex from July 23, 1980, when she first obtained the Product, until mid-November 1980. At trial defendant presented testimony to suggest that Ms. Maihafer's statements concerning the amount of the Product she obtained were inconsistent with her testimony about her frequency of sexual intercourse. After considering all the evidence, however, the Court found most convincing the positive testimony of Ms. Maihafer, corroborated by Gary Wells, that she had properly used the Product each time they had sex during this interval.

Next, the Court found that plaintiffs had presented insufficient evidence to establish that the Product proximately caused Katie Wells' cleft lip and hypoplasia of the right optic nerve. Plaintiffs' most persuasive expert witness, Dr. Buehler, could not state with a reasonable degree of medical certainty that the cleft lip and eye defect were caused by the Product, although he did not rule out that possibility. The Court found that plaintiffs' other evidence did not prove to a reasonable degree of medical certainty that the Product caused these two defects.

With respect to the birth defects of Katie Wells' left arm and shoulder and right hand, the Court reached a different conclusions. The Court found that plaintiffs had presented competent and credible medical and scientific evidence that

showed to a reasonable degree of medical certainty that the Product proximately caused these defects. This conclusion was reached by Doctors Buehler and Sutherland - two physicians who were well-qualified to address the issue of causation, who had examined Katie Wells themselves, and who were highly credible witnesses. Dr. Holbrook's testimony also supported this conclusion.

Defendant attempted to rebut plaintiffs' evidence of causation through various scientific studies and reports and through its own expert witnesses. Although the studies on which defendant relied failed to detect an association between spermicides and birth defects, some of defendants' own experst testified that these studies do not rule out all possibility that spermicides can cause birth defects. See Transcript at 1411-13

(Testimony of Dr. Stolley), 1653-54 (Testimony of Dr. Brent). Thus, although the Court assigned weight to the studies offered by defendant, in calculating this weight the Court kept in mind these studies' limitations. Again, the Court emphasizes that its ultimate focus was the birth defects suffered by Katie Wells. Plaintiffs' burden of proving that Katie Wells' defects were caused by the Product did not necessarily require them to produce scientific studies showing a statistically significant association between spermicides and congenital malformations in a large population. In addition, the studies by Jick and others that indicated a possible link between spermicides and birth defects further undermine any suggestion that the studies relied on by defendant conclusively show that its Product does not cause birth

defects. Consequently, the Court found the studies to be inconclusive on the ultimate issue of whether the Product caused Katie Wells' birth defects.[38]

Thus, the Court looked to the other evidence concerning causation and found that the testimony of plaintiffs' experts conflicted with that of defendant's experts on critical points. Plaintiffs' experts had suggested several possible "mechanisms" of causation, and the Court found Dr. Buehler's explanation the most

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38 In finding the studies offered by defendant inconclusive on the issue of causation, the Court did not need to consider as substantive evidence the studies offered by plaintiff to suggest causation. Of course, the Oechsli study, the Smith study, the Buttar study on teratogenicity, and the Jick study all support this finding. As discussed below, the Court did consider the Oechsli and Smith studies in making its decision on the issue of failure to warn.

plausible of these.[39] Dr. Buehler stated his opinion, to a reasonable degree of medical certainty, that the defects of Katie Wells' left shoulder and arm and right hand were caused by a vascular disruption. He explained that the smoothness of the left shoulder and the underdevelopment of the clavicle and scapula indicated that an interruption in the blood supply to the developing limb had caused these defects. Similarly, the absence of the middle portion of Katie Wells' finger suggested to Dr. Buehler

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39 In finding one mechanism more likely than the others suggested by plaintiffs' experts, the Court does not discount the possible validity of those alternative explanations. Instead, the Court point out that, as more than one expert witness in this case has testified, it is not unusual that scientists sometimes cannot identify the precise mechanism by which even a known teratogen, such as thalidomide, causes birth defects.

that the missing part had lost its blood supply and had been reabsorbed.

In contrast, Dr. Brent, testifying for defendant, stated that the most likely cause of these defects was the amniotic band syndrome, in which a band of material becomes wrapped around a body part and essentially amputates it. Dr. Buehler, however, disagreed strongly with this explanation. He maintained that if banding had occurred at Katie Wells' left shoulder, the clavicle and scapula would not have been underdeveloped, but would have been normal-sized. Further, according to Dr. Buehler, her fingers did not show the amputation expected to result from banding. Dr. Brent never addressed these criticisms to the Court's satisfac-

tion.[40] In light of these criticisms and of Dr. Brent's apparent bias, as discussed above, the Court found Dr. Buehler's opinion about vascular disruption to be the most reasonable and believable explanation of the cause of the defects of Katie Wells' arm and hand.

The testimony of the expert witnesses conflicted on several other key points. Dr. Buehler concluded that the spermicide was the most likely cause of the irritation of the vascular supply that resulted in these birth defects. One factor on which he relied was that Ms. Maihafer had continued to use the spermicide after conception through the

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40 Although the Court recognized that defendant had no burden to prove the actual cause of these birth defects, Dr. Brent did propose his own theory of causation. The Court considered the criticisms of that theory in determining how much weight to attribute to his testimony.

time of development of the limb buds, which according to Dr. Buehler are visible by four and one-half to five weeks after conception. Dr. Brent, on the other hand, ruled out the possibility that these defects resulted from an injury to the embryo during the "all or none" period of the first seventeen days after conception. Further, Dr. Brent suggested that exposure before the twenty-fourth day would produce no limb development abnormalities.

Once again, the Court found the conclusions of plaintiffs' expert more persuasive. One basis of this finding was the contrast between Dr. Brent's apparent bias and the absence of any discernible bias in Dr. Buehler's testimony. Another basis was that even assuming the validity of the "all or none" theory - which Dr. Buehler testified has

been deemed "simplistic" by some authorities[41] - based on uncontradicted evidence the Court found that Ms. Maihafer had used the spermicide after the seventeen-day "all or none" period and, quite likely, even after the twenty-fourth day following conception. The timing of Ms. Maihafer's use of the Product is consistent with Dr. Buehler's conclusion that the vascular disruption must have occurred "much earlier" than four weeks after conception. Transcript at 275-76.

Similarly, plaintiffs' and defendant's experts disagreed over absorption of the Product. Plaintiffs introduced studies indicating that absorption does occur, and at least one expert witness - Dr. Sutherland - testified with a reasonable degree of medical certainty that the

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41 Transcript at 305.

Product is absorbed. Transcript at 664. Testifying for defendant, Dr. Malyk attacked the validity of these studies, proclaiming the superiority of Ortho's own studies that detected no absorption, and Dr. Brent urged that absorption could not have led to these birth defects. Again, the Court found plaintiffs' evidence competent, credible, and free of the bias that the Court detected in the testimony of Doctors Malyk and Brent. Thus, the Court found plaintiffs' evidence concerning absorption more believable than defendant's.

In addition, defendant had hoped that the findings of two government review panels would negate plaintiffs' evidence of causation. The Court found that the reports of these panels - like the various scientific studies already addressed - were entitled to some weight,

but could not show conclusively whether Katie Wells' birth defects were caused by the Product. In the Court's view, the findings of the FMHDAC, which specifically addressed the possible teratogenicity of spermicides, are less persuasive because Dr. Brent, a participant in that inquiry, assisted defense counsel in this case before the December 1983 Committee meeting and did not disclose to the Committee his prior involvement in this lawsuit.

The preceding discussion by no means exhausts the issues that the Court considered in arriving at its finding on the issue of causation. Rather, it illustrates some important aspects of the evidence presented in this case. Plaintiffs presented competent evidence that the Product had proximately caused Katie Wells' birth defects, and this evidence

generally was credible. Defendant offered evidence that the Product was not the proximate cause of these defects, yet this evidence often lacked credibility because it reflected bias or inconsistency. Accordingly, the Court found to a reasonable degree of medical certainty that the Product had proximately caused the birth defects of Katie Wells' left shoulder and arm and right hand.

The Court also found that at the time Ms. Maihafer obtained the Product in 1980, defendant was negligent in failing to warn that an increased risk of birth defects might accompany the use of the Product. Various articles and studies suggesting the possibility of such a risk were available to defendant prior to July 1980. These included the 1975 article "Vaginal Contraceptives - A Time for Reappraisal?"; the 1976 Oechsli study;

and the 1977 Smith study. Although defendant suggested that the unpublished Oechsli study was not available, the Court found otherwise; the study was cited in the Harlap article published in March 1980, and Doctors Sutherland and Gourley testified that the study would have been available to defendant through several means.[42]

Because these studies were available to defendant before July 1980, the Court found that defendant had actual or constructive knowledge that the Product might cause birth defects. This knowledge gave rise to a duty by defendant to warn consumers and certain health professionals of this possible risk. The

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42 As noted previously, Dr. Gourley testified that if Ortho did not have the Oechsli study in 1976, "somebody was asleep at the wheel." Transcript at 873.

Ccurt agreed with Dr. Gourley's opinion that defendant should have given such a warning no later than 1977, as soon as there was a "hint" of a possibility that the Product causes birth defects. Transcript at 870. At the time Ms. Maihafer obtained the Product in 1980, defendant had given no such warning; neither the package insert nor the label contained any warning that the Product might increase the risk of birth defects or that a user should discontinue use and consult a physician immediately if she suspects she is pregnant. Defendant's failure to warn fell beneath the standard of ordinary and reasonable care under the circumstances. Thus, the Court found that defendant was negligent in failing to warn of this potential danger.

The Court also found that defendant's failure to warn proximately caused

Katie Wells' arm and hand defects. Although an adequate warning about the use of the Product after pregnancy is suspected may not have enabled Ms. Maihafer to use the Product safely, it could have enabled her to decide whether to use the Product at all. Experts for defendant expressed dismay that a warning might have prompted users of the Product to switch to other types of contraceptives less "appropriate" for them. This "appropriateness," however, should be determined by users of the Product and their physicians with access to all relevant information, not by manufacturers. Had a proper warning been given, Ms. Maihafer may well have selected an alternative, less dangerous means of birth control. Further, if defendant had warned of this increased risk, Ms. Maihafer could have consulted her physician for tests early

in her pregnancy to determine whether the fetus was developing normally[43] and, if not, she would have had the option of terminating her pregnancy.

CONCLUSIONS OF LAW

Under both the negligent failure to warn and the strict products liability theories of recovery, plaintiffs bear the burden of establishing that defendant's Product proximately caused plaintiff's injuries. Talley v. City Tank Corporation, 158 Ga. App. 130, 134 (1981). When medical causation is at issue,

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43 Dr. Buehler testified that after the Jick study was published, he began to recommend that mothers who used spermicides around the time of conception have ultrasound tests at twelve to fourteen weeks after conception to determine whether or not limb defects were present. Transcript at 261. If Ortho had provided such a warning, Ms. Maihafer would have had the opportunity to undergo similar testing.

plaintiffs must prove causation to a "reasonable degree of medical certainty." See Parrott v. Chatham County Hospital Authority, 145 Ga. App. 113, 115 (1978); Robertson v. Emory University Hospital, 611 F.2d 604, 608 n.13 (5th Cir. 1980); Watson v. United States, 346 F.2d 52, 54 (5th Cir. 1965), cert. denied, 382 U.S. 976 (1966). Plaintiffs may not recover if the Court, acting as factfinder, determines that there was only a "bare possibility" that the Product caused these birth defects or if other theories of causation are equally plausible. See Maddox v. Houston County Hospital Authority, 158 Ga. App. 283, 284 (1981).

As discussed above, plaintiffs carried their burden of proof regarding causation. The Court found that plaintiffs had presented competent and credible medical and scientific evidence that

showed to a reasonable degree of medical certainty that the Product proximately caused the birth defects of Katie Wells' left arm and shoulder and right hand.

According to Georgia law of negligence, a manufacturer having actual or constructive knowledge that use of its product entails non-obvious, foreseeable dangers has a duty to warn users of its product of these dangers. See Rhodes v. Interstate Battery System of America, Inc., 722 F.2d 1517, 1519 (11th Cir. 1984); Kicklighter v. Nails by Janee, Inc., 616 F.2d 734, 740 n.4 (5th Cir. 1980); Beam v. Omark Industries, Inc., 143 Ga. App. 142, 145 (1977). This duty, which rises "at the time of sale and delivery," Beam, 143 Ga. App. at 145, is to exercise reasonable care in warning users of the product of such dangers.

J.C. Lewis Motor Co. v. Williams, 85 Ga. App. 538, 541-42 (1952).

Plaintiffs satisfied each of these elements of this theory of negligence. The Court found that defendant had actual or constructive knowledge that the Product might cause an increased risk of birth defects because various studies suggesting this risk were available to defendant well before Ms. Maihafer first obtained the Product in 1980. Based on credible expert testimony presented by plaintiffs, the Court found that defendant's failure to warn fell beneath the standard of ordinary care required under the circumstances. Finally, the Court found that defendant's failure to warn proximately caused the birth defects previously identified.

The basis for strict products liability in Georgia is O.C.G.A. § 51-1-11,

which provides in part that a natural person may recover against a manufacturer when he suffers injury "because the [product] when sold by the manufacturer was not merchantable and reasonably suited for the use intended, and its condition when sold is the proximate cause of the injury sustained." The phrase "not merchantable and reasonably suited for the use intended," as used in this statute, means "defective." Giordano v. Ford Motor Co., 165 Ga. App. 644, 645 (1983).

A manufacturer's failure to warn of the dangers in using a product may constitute a defect in the product for purposes of strict liability when the manufacturer "has reason to anticipate that danger may result from a particular use." Center Chemical Co. v. Parzini, 234 Ga. 868,

869-70 (1975) (quoting Restatement (Second) of Torts § 402A comment h (1965)).

Thus, the elements of plaintiffs' strict liability theory are essentially the same as the elements of their theory of negligent failure to warn. Again, plaintiffs established each of these elements. The Court found that at the time plaintiffs established each of these elements. The Court found that at the time of Ms. Maihafer's purchase of the Product in 1980, defendant knew or should have known of the potential danger that the Product might cause birth defects and that this potential danger required a warning. The absence of such a warning constituted a defect in the Product. As the Court has already discussed at length, defendant's failure to warn proximately caused the birth defects of Katie Wells' left arm and shoulder and right hand. In

sum, the facts proven by plaintiffs at trial entitle them to recover under theories of negligent failure to warn and strict liability.

FINDINGS AND CONCLUSIONS CONCERNING DAMAGES

A. Plaintiff Katie Wells

Based on the testimony of Dr. Brown and Dr. Bussey, the Court awarded Katie Wells damages for loss of future earnings[44] in the amount of $415,000. Dr. Brown's calculations had produced a similar figure under the assumptions that Katie Wells would have completed college, that her "work life expectancy" would have been 27.91 years, and that she is

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44 Although plaintiffs sought damages for Katie Wells' "loss of earning capacity," the evidence they presented was directed to her loss of future earnings. Damages for "loss of earning capacity," a species of general damages, were included in the Court's award to Katie Wells of damages for pain and suffering.

totally disabled. Given the Court's own observations and the testimony that Katie Wells is bright and intelligent, the Court agreed that she likely would have completed college. Although the Court found that defendant is liable only for the birth defects of her left arm and shoulder and right hand, any reduction for that portion of her disability not attributable to the Product would be offset by the Court's finding that, given her mother's achievements and her own intelligence, her work life expectancy probably would have been considerably longer than Dr. Brown's conservative assumption of 27.91 years.

Based on Dr. Buehler's testimony concerning Katie Wells' future medical expenses, including regular replacement of prosthetic devices and modification of work and living space, the Court awarded

Katie Wells $1.2 million for future medical expenses associated with those birth defects proximately caused by the Product.

Based on the Court's observations of Katie Wells during trial and the films and testimony depicting the difficulties she faces and will continue to face in performing even ordinary activities, the Court awarded Katie Wells $3 million for past and future pain and suffering caused by the birth defects attributable to the Product.

B. Plaintiff Mary Maihafer

Ms. Maihafer interrupted her college teaching career for approximately two years after Katie Wells' birth so that she could devote her full time and attention to taking care of the child. The Court found that this interruption was proximately caused by the birth defects

attributable to the Product, and, therefore, that Ms. Maihafer is entitled to compensation for her lost earnings during that period. Based on the evidence of her earnings before and after this interruption, the Court awarded Ms. Maihafer $36,000 for lost earnings.[45]

Plaintiffs also sought reimbursement for certain past medical expenses incurred by Ms. Maihafer for the treatment of Katie Wells. At the conclusion of trial, the Court announced that it would award plaintiffs $3,475 in past medical expenses. The Court now modifies that award, which was based on the expenses of surgery on Katie Wells' cleft lip and right hand. Because the surgery was per-

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45 Although plaintiffs prayed for damages for Ms. Maihafer's "loss of earning capacity," it was clear from the evidence presented that they actually were seeking to recover Ms. Maihafer's lost earnings.

formed at one time, the Court cannot determine what portion of those expenses may be attributed solely to her right hand. Plaintiffs have agreed to forego all past medical expenses except the $30 cost of an orthopedic surgeon's examination of Katie Wells. Consequently, the award to Ms. Maihafer for past medical expenses is reduced to $30.

In addition, plaintiffs sought damages for Ms. Maihafer's alleged physical pain and suffering and mental anguish. The Court found no evidence of physical pain and suffering by Ms. Maihafer, but did find that she suffered substantial mental distress as a result of the birth defects attributable to the Product.

The parties disagreed over whether Georgia law would allow recovery for Ms. Maihafer's mental distress. Georgia law

provides that when a plaintiff suffers a "physical injury" or "pecuniary loss," that plaintiff's compensatory damages may include recovery for the accompanying mental pain and suffering, even if the tortious conduct complained of is merely negligent. Western Cemetery, Inc. v. Blanchard, 234 Ga. 540, 543 (1975).

The Court found that Ms. Maihafer is entitled to recover for her mental distress, mortification, and disappointment at the birth of her deformed child. As a result of defendant's tortious conduct, Ms. Maihafer suffered pecuniary loss in the form of lost earnings and those of Katie Wells' medical expenses that are attributable to the Product. See Westview Cemetery, Inc. v. Blanchard, 234 Ga. at 543. Because of this pecuniary loss, Ms. Maihafer may recover damages for the accompanying mental pain and suffering.

Alternatively, Ms. Maihafer may recover damages for her mental anguish because the "physical injury" requirement is satisfied here. According to the Court's research, the term "physical injury" as used in the Georgia cases is much broader than a literal reading of that phrase suggests. The "physical injury" need not produce any actual physical hurt or damage to the plaintiff seeking recovery for mental anguish.[46] Some Georgia cases more accurately have re-

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46 One Georgia case relying on this proposition, Christy Brothers Circus v. Turnage, 38 Ga. App. 581, 581 (1928), was cited by Prosser in his discussion of how relatively minor contacts often have been held to satisfy the "physical injury" requirement. The court in Christy Brothers Circus upheld an award of damages for mental anguish when the only "physical injury" to plaintiff was that defendant's horse had defecated into plaintiff's lap. Id. See W. Prosser, Handbook of the Law of Torts § 54 at 331 (4th ed. 1971).

ferred to this requirement as the "impact rule." As defined in Strickland v. Hodge, 134 Ga. App. 909, 910 (1975), the "impact rule" requires that defendant's negligent conduct result in "actual bodily contact" to the plaintiff.

In this case, defendant's negligent conduct - its failure to warn - resulted in several "bodily contacts" with Ms. Maihafer. One was Ms. Maihafer's insertion of the diaphragm and spermicide into her body. As discussed above, Ms. Maihafer may not have used the Product at all if it had contained an adequate warning of an increased risk of birth defects. In addition, according to all the various "mechanisms" suggested by plaintiffs' experts in explaining how the Product might have caused Katie Wells' birth defects i.e., by damaging the sperm, the unfertilized or fertilized

egg, or the developing fetus - Ms. Maihafer's body was the conduit through which the damage occurred. Consequently, the Court concluded that sufficient "bodily contact" or "impact" had occurred as a result of defendant's negligent conduct to entitle Ms. Maihafer to recover for her mental distress.[47] The Court

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47 The award of damages for Ms. Maihafer's mental distress is consistent with the rationale underlying the "physical injury" requirement or "impact rule." As Prosser has observed, "It is now more or less generally conceded that the only valid objection against recovery for mental injury is the danger of vexatious suits and fictitious claims, which has loomed very large in the opinions as an obstacle." Prosser, supra note 46, § 54 at 328 (quoted in Hamilton v. Powell, Goldstein, Frazer & Murphy, 252 Ga. 149, 151-52 (1984) (Clarke, J., dissenting). No one would argue that a mother's shock and disappointment at the birth of her deformed child could be fictitious.

(footnote continued on next page)

awarded Ms. Maihafer $500,000 for her mental distress, mortification, and disappointment at the time of Katie Wells' birth for those birth defects attributable to the Product.

DEFENDANT'S MOTION TO REOPEN

On May 13, 1985, after the Court had begun work on these findings of fact and conclusions of law, defendant moved the Court to reopen the evidence and to re-consider its announced decision on the basis of three additional articles. Plaintiffs oppose this motion.

(footnote continued from previous page)

This award is also consistent with statement in Davis v. Murray, 29 Ga. App. 120, 120 (1922), that a mother is entitled to recover damages for her mental suffering on account of her mortification and disappointment at the birth of a deformed child when defendant's negligence has caused the deformities.

As defendant acknowledged in its brief, decisions on motions to reopen are committed to the sound discretion of the trial court. Zenith Radio Corp. v. Hazeltine Research, Inc., 401 U.S. 321, 331-32 (1971); Unibed States v. One 1972 44' Striker, Bonanza, 753 F.2d 867, 869 (11th Cir. 1985). The Court has determined that reopening the evidence would cause undue hardship and expense for plaintiffs, who would be forced to bring back their expert witnesses to testify about the conclusions that they would draw from these articles. Further, as a case cited by defendant points out, a motion to reopen is less favorably received after the court has rendered its decision, even if formal findings of fact and conclusions of law have not been made and judgment entered. Caracci v. Brother International Sewing Machine

Corp. of La., 222 F. Supp. 769, 771 (E.D. La. 1963), aff'd, 341 F.2d 377 (5th Cir. 1965). Every trial must end at some point. No circumstances present in this case, which was competently and thoroughly tried, warrant reopening the evidence more than three months after trial and after a decision by this Court.[48] Thus, the motion to reopen will be denied.

SUMMARY

The Court DENIES defendant's motion to reopen the evidence and, in accordance with these findings and conclusions, DIRECTS that judgment be entered in favor of plaintiffs in the following amounts:

---

48 Even if the Court were to reopen the evidence, the Court's review of these articles suggests that the outcome of the case would be unchanged.

(1) Katie Wells:	
(a) loss of future earnings	$415,000
(b) future medical expenses	$1,200,000
(c) past and future pain and suffering	$3,000,000
(2) Mary Maihafer	
(a) medical expenses of Katie Wells	$ 30
(b) loss of earnings	$ 36,000
(c) mental distress	$500,000

The Court further DIRECTS that plaintiffs shall recover their costs of this action from defendant.

IT IS SO ORDERED, this 29th day of July, 1985.

/s/ Marvin H. Shoob
Marvin H. Shoob, Judge
United States District Court
Northern District of Georgia

U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
FILED
AUGUST 15, 1986
LUTHER D. THOMAS, CLERK
BY: DEPUTY CLERK

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 85-8683

D.C. Docket No. 82-1921

KATIE LAUREL WELLS, ET AL.,

Plaintiffs-Appellees,

versus

ORTHO PHARMACEUTICAL CORPORATION,

Defendant-Appellant.

- - - - - - - - - - -

Appeal from the United States
District Court for the Northern
District of Georgia

- - - - - - - - - - -

Before GODBOLD, Chief Judge, VANCE, Circuit Judge, and THOMAS[1], Senior District Judge.

J U D G M E N T

This cause came on to be heard on the transcript of the record from the United States District Court for the Northern District of Georgia, and was argued by counsel;

ON CONSIDERATION WHEREOF, it is now here ordered and adjudged by this Court that the judgment of the said District Court in this cause be and the same is hereby, AFFIRMED and MODIFIED in part, and that this cause be and the same is hereby, REMANDED to said District Court with instructions in accordance with the opinion of this Court.

It is further ordered that defendant-appellant pay to plaintiffs-appellees, the costs on appeal to be taxed by the Clerk of this Court.

---

1 Honorable Daniel H. Thomas, Senior U.S. District Judge for the Southern District of Alabama, sitting by designation.

Entered: May 6, 1986

For the Court:
Spencer D. Mercer, Clerk

By: /s/ Miguel J. Cortez, Jr.
Deputy Clerk

A True Copy - Attested
Clerk, U.S. Court of Appeals
Eleventh Circuit

By /s/ Wright W. Briggs
Deputy Clerk
Atlanta, Georgia
ISSUED AS MANDATE: Aug. 14, 1986

FILED IN CLERK'S OFFICE
U.S.D.C. Atlanta
September 11, 1986
Luther D. Thomas, Clerk
By: Deputy Clerk

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 85-8683

D.C. Docket No. 82-1921

KATIE LAUREL WELLS, ET AL.,

Plaintiffs-Appellees,

versus

ORTHO PHARMACEUTICAL CORPORATION,

Defendant-Appellant.

- - - - - - - - - - -
Appeal from the United States
District Court for the Northern
District of Georgia
- - - - - - - - - - -

Before GODBOLD, Chief Judge, VANCE, Circuit Judge, and THOMAS*, Senior District Judge.

---

* Honorable Daniel H. Thomas, Senior U.S. District Judge for the Southern District of Alabama, sitting by designation.

A M E N D E D J U D G M E N T

This cause came on to be heard on the transcript of the record from the United States District Court for the Northern District of Georgia, and was argued by counsel;

ON CONSIDERATION WHEREOF, it is now here ordered and adjudged by this Court that the judgment of the said District Court in this cause be and the same is hereby, AFFIRMED and MODIFIED in part, and that this cause be and the same is hereby, REMANDED to said District Court with instructions in accordance with the opinion of this Court;

Interest on the judgment in the modified amount shall accrue from the original date of the District Court Judgment;

It is further ordered that defendant-appellant pay to plaintiffs-appellees, the costs on appeal to be taxed by the Clerk of this Court.

Entered: May 6, 1986 For the Court:
Miquel J. Cortez, Clerk

By: /s/ Miguel J. Cortez, Jr.
Deputy Clerk

A true copy - Attested
Clerk, U.S. Court of Appeals
Eleventh Circuit

By /s/ Wright W. Briggs
Deputy Clerk
Atlanta, Georgia
ISSUED AS MANDATE: Aug. 14, 1986

U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
FILED
JUN 27 1986
MIGUEL J. CORTEZ
CLERK

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 85-8683

KATIE LAUREL WELLS, et al.,

Plaintiffs-Appellees,

versus

ORTHO PHARMACEUTICAL CORPORATION,

Defendant-Appellant.

Appeal from the United States District Court for the Northern District of Georgia

---

O R D E R:

The motion of E. R. Squibb & Sons, Inc. to file a brief as amicus curiae is GRANTED.

/s/ ROBERT S. VANCE
UNITED STATES CIRCUIT JUDGE

U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
FILED
JUNE 27, 1986
MIGUEL J. CORTEZ
CLERK

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 85-8683

KATIE LAUREL WELLS, ET AL.,

Plaintiffs-Appellees,

versus

ORTHO PHARMACEUTICAL CORPORATION,

Defendant-Appellant.

- - - - - - - - - - -

Appeal from the United States
District Court for the Northern
District of Georgia

- - - - - - - - - - -

ON PETITION FOR REHEARING AND SUGGESTION FOR REHEARING EN BANC (Opinion May 6, 11 Cir., 1986, ____ F.2d _____).

(June 27, 1986)

Before GODBOLD, Chief Judge, VANCE, Circuit Judge, and THOMAS*, Senior District Judge.

---

* Honorable Daniel H. Thomas, Senior U.S. District Judge for the Southern District of Alabama, sitting by designation.

PER CURIAM:

(X) The Petition for Rehearing is DENIED and no member of this panel nor other Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure; Eleventh Circuit Rule 26), the Suggestion for Rehearing En Banc is DENIED.

( ) The Petition for Rehearing is DENIED and the Court having been polled at the request of one of the members of the Court and a majority of the Circuit Judges who are in regular active service not having voted in favor of it (Rule 35, Federal Rules of Appellate Procedure; Eleventh Circuit Rule 26), the Suggestion for Rehearing En Banc is also DENIED.

( ) A member of the Court in active service having requested a poll on the reconsideration of this cause en banc, and a majority of the judges in active service not having voted in favor of it, rehearing en banc is DENIED.

ENTERED FOR THE COURT:

/s/ Robert S. Vance
United States Circuit Judge

U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
FILED
JUNE 27, 1986
MIGUEL J. CORTEZ
CLERK

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 85-8683

KATIE LAUREL WELLS, ET AL.,

Plaintiffs-Appellees,

versus

ORTHO PHARMACEUTICAL CORPORATION,

Defendant-Appellant.

- - - - - - - - - - -

Appeal from the United States
District Court for the Northern
District of Georgia

- - - - - - - - - - -

ON PETITION(S) FOR REHEARING
(June 27, 1986)

Before GODBOLD, Chief Judge, VANCE, Circuit Judge, and THOMAS*, Senior District Judge.

---

* Honorable Daniel H. Thomas, Senior U.S. District Judge for the Southern District of Alabama, sitting by designation.

PER CURIAM:

The Petition(s) for rehearing filed by appellees Katie Laurel Wells, et al. is denied.

ENTERED FOR THE COURT:

/s/
United States Circuit Judge

UNITED STATES COURT OF APPEALS
ELEVENTH CIRCUIT
50 Spring Street, S.W.
Atlanta, Georgia 30303-3147

Miguel J. Cortez
Clerk

In Replying
Give Number
Of Case And
Names of
Parties

TO ALL COUNSEL OR PARTIES LISTED BELOW:

No. 85-8683 KATIE LAUREL WELLS, et al.
v. ORTHO PHARMACEUTICAL
CORPORATION (C82-1921A)

MANDATE STAYED TO AND INCLUDING
August 8, 1986

This Court has this day granted a stay of the issuance of the mandate to the date as shown above. If during the period of the stay there is filed with this office a notice from the Clerk of the Supreme Court that the party who has obtained the stay has filed a petition for the writ in that Court, the stay shall continue until final disposition by the Supreme Court. Upon the filing of a copy of an order of the Supreme Court denying the petition for writ of certiorari, the mandate shall issue immediately under Rule 41, FRAP.

Rule 19.1 of the Supreme Court, effective June 30, 1980, states that a request to certify the record prior to action by the Supreme Court on the petition for certiorari should not be made as a matter of course but only when the record is deemed essential to a proper understanding of

the case by that Court. However, this Court will not transmit the record to the Supreme Court until that court requests to review it.

A copy of the opinion, judgment, or Rule 23 Decision, and denial of rehearing are still required by the Supreme Court to be incorporated as an appendix to your petition.

Very truly yours,

MIGUEL J. CORTEZ, CLERK

By_____
Deputy Clerk

cc: Robert J. Pennington
Barry L. Shapiro
Marc S. Skein
James C. Simmons, Jr.

U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
FILED
AUGUST 14, 1986
MIGUEL J. CORTEZ
CLERK

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 85-8683

KATIE LAUREL WELLS, ET AL.,

Plaintiffs-Appellees,

versus

ORTHO PHARMACEUTICAL CORPORATION,

Defendant-Appellant.

- - - - - - - - - - -

Appeal from the United States
District Court for the Northern
District of Georgia

- - - - - - - - - - -

O R D E R :

( ) The motion of _____
_____
for __ stay __ recall and stay
of the issuance of the mandate
pending petition for writ of
certiorari is DENIED.

( ) The motion of _____
for __ stay __ recall and stay
of the issuance of the mandate

pending petition for writ of certiorari is GRANTED to and including _____, the stay to continue in force until the final disposition of the case by the Supreme Court, provided that within the period above mentioned there shall be filed with the Clerk of this Court the certificate of the Clerk of the Supreme Court that the certiorari petition has been filed. The Clerk shall issue the mandate upon the filing of a copy of an order of the Supreme Court denying the writ, or upon the expiration of the stay granted herein, unless the above mentioned certificate shall be filed with the Clerk of this Court within that time.

( ) The motion of appellant, ORTHO PHARMACEUTICAL CORPORATION, for a further stay of the issuance of the mandate is GRANTED to and including _____ _____, under the same conditions as set forth in the preceding paragraph.

(X) IT IS ORDERED that the motion of appellant, ORTHO PHARMACEUTICAL for a further stay of the issuance of the mandate is DENIED.

/s/ Robert S. Vance
UNITED STATES CIRCUIT JUDGE

Supreme Court, U.S.
FILED
OCT 17 1986
JOSEPH F. SPANIOL, JR.
CLERK

No. 86-513

IN THE

Supreme Court of the United States

OCTOBER TERM, 1986

ORTHO PHARMACEUTICAL CORPORATION,

Petitioner,

v.

KATIE LAUREL WELLS (infant), BY HER MOTHER AND NEXT FRIEND, MARY MAIHAFER, AND FATHER, GARY S. WELLS,

and

MARY MAIHAFER (Individually),

Respondents.

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

JAMES C. SIMMONS, JR.
Counsel of Record

SIMMONS & TOLIVER
JAMES C. SIMMONS, JR.
A. LEROY TOLIVER
MARILYN F. DYE
3355 LENOX ROAD
LENOX CENTER, SUITE 800
ATLANTA, GEORGIA 30326
Counsel for Respondents Katie Laurel Wells, et al.

QUESTIONS PRESENTED

1. Whether Petitioner is merely attempting to argue once again the facts previously heard and adjudicated without alleging a significant issue for review or showing any departure from the course of accepted judicial proceedings?

2. Whether the United States Court of Appeals, Eleventh Circuit, created a new oral testimony standard or conflict among the circuits?

3. Whether Petitioner's complaints about credibility determinations and deference to governmental committee findings are applicable to the facts of this case?

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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1986

ORTHO PHARMACEUTICAL CORPORATION,

Petitioner,

v.

KATIE LAUREL WELLS (infant), BY HER MOTHER AND NEXT FRIEND, MARY MAIHAFER, AND FATHER, GARY S. WELLS,

and

MARY MAIHAFER (Individually),

Respondents.

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

The Respondents respectfully request this Court deny the Petition for Writ of Certiorari seeking review of the Eleventh Circuit's Opinion in this case.

STATEMENT OF THE CASE INCLUDING THE NATURE OF THE PROCEEDINGS AND THE DISPOSITION BELOW

This diversity product liability action alleges Petitioner's product, Ortho-Gynol Contraceptive Jelly, after failing to prevent conception caused birth defects in the child thus conceived.

Katie Wells, the daughter of Mary Maihafer and Gary Wells, was born on July 1, 1981 with several birth defects, including the complete lack of a left arm with only partial development of her left clavicle and shoulder, abnormal formation of her right hand, a cleft lip and nostril deformity.

On September 2, 1982, Katie Wells, by Mary Maihafer and Gary S. Wells, and Mary Maihafer, Individually, instituted their action against Petitioner Ortho Pharmaceutical Corp. (Ortho). The Complaint stated a cause of action for negligence, strict product liability, intentional tort and breach of warranty. In essence, Respondents alleged that: (1) Ortho-Gynol contraceptive jelly, a spermicide, caused Katie Wells' birth defects; (2) Ortho's product contained no warning that it could cause birth defects; (3) Ortho's product was defective for lack of adequate warning; (4) Ortho negligently failed to warn; and (5) Ortho's defective product and negligent failure to warn proximately caused the birth defects. The Complaint sought damages for Katie Wells' pain and suffering, medical expenses and disability, as well as Mary Maihafer's mental distress and lost wages. Respondents also sought punitive damages.

The parties subsequently agreed to waive a jury and the case was tried to the District Court (Honorable Marvin H. Shoob) from January 8 through January 22, 1985. Both sides presented substantial expert witness testimony. Their

opinions often were diametrically opposed relative to the major elements of the case. In an effort to resolve these direct conflicts in the experts' opinions, the trial judge "regularly examined daily transcripts of much of the expert testimony and spent an entire weekend reviewing the studies introduced." *Wells v. Ortho Pharmaceutical Corp.*, 615 F. Supp. 262, 266 (N.D. Ga. 1985); A-33.[1]

The trial court found that Respondents had proven to a reasonable degree of medical certainty the birth defects of Katie Wells' left arm and shoulder and right hand were proximately caused by Ortho's product. Finding Respondents also met the other prima facie elements of their negligence and product liability theories, the trial court awarded damages exceeding $5.1 million.

The trial court, some six months later, entered its Order detailing extensive Findings of Fact and Conclusions of Law. *Wells*, 615 F. Supp. 262; A-29-194. The Order included a denial of Ortho's Motion To Reopen. Final Judgment was entered on August 1, 1985.

The Petitioner filed its Notice of Appeal in the United States Court of Appeals for the Eleventh Circuit on August 29, 1985. On appeal, Ortho raised the questions presented here by strenuously urging the court to focus its attention on a number of "studies". Ortho propounded then and now that their "studies" should singularly control the outcome in this product liability action. The Eleventh Circuit Panel, after thorough evaluation and analysis of the same issues presented here, issued a detailed opinion finding these claims to be without merit and affirming the District

---

1. Citations to "A" herein refer to Petitioner's Appendix filed with its present Petition; "T" refers to the trial transcript; "OP" refers to Ortho's Petition for Certiorari; and "OAB" refers to Ortho's Appellate Brief.

Court's Judgment in favor of Respondents.[2] *Wells*, 788 F.2d 741.

The Eleventh Circuit denied Ortho's Petition for Rehearing and suggestion for rehearing *en banc* on June 27, 1986.[3] *Wells*, 795 F.2d 89; A-203-205.

REASONS FOR DENYING THE WRIT

I.

PETITIONER ATTEMPTS TO ARGUE ONCE AGAIN THE FACTS PREVIOUSLY HEARD AND ADJUDICATED WITHOUT ALLEGING A SIGNIFICANT ISSUE FOR REVIEW OR SHOWING ANY DEPARTURE FROM THE COURSE OF ACCEPTED JUDICIAL PROCEEDINGS.

Petitioner seeks to retry the merits of its case. The first twelve (12) pages of Petitioner's Brief argue facts previously presented to the trial court. Actual trial evidence in the form of several studies is presented by Petitioner in its "Lodging" with this Court. This "Lodging" of evidence is a continuance of Petitioner's attempt to argue that which has been decided by a competent trier of fact. A Writ of Certiorari is "not [to be used] to review evidence and discuss specific facts." *United States v. Johnston*, 268 U.S. 220, 227 (1925).

Petitioner's blatant statement in the first sentence of its Statement Of The Case designed to pique the attention of its reader that "with the exception of Plaintiffs' experts in this case, no scientist has ever publicly expressed an

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2. The Appellate Court reduced the total amount of the Award but such reduction is not part of Petitioner's present Argument.

3. Respondents' Petition for Rehearing on the damage issue was denied on the same date. A-206-208.

opinion that spermicides cause birth defects," overlooks its *own* "Lodging" with this Court at Page 24 of a *JAMA* article which makes just such a statement. This *Journal of the American Medical Association* article published April 3, 1981, is authored by several scientists (Hershel Jick, M.D.; Alexander M. Walker, M.D., MPH; Kenneth J. Rothman, Dr.PH; et al.) who did not testify as experts for the Plaintiffs. *They publicly expressed* at page 26:

COMMENT

> The present data show a positive association between vaginal spermicide use and certain congenital disorders, namely, limb reduction deformities, neoplasms, chromosomal abnormalities, and hypospadias.

To continue its fact-bound argument before this Court in itself falls outside the guidelines of Supreme Court Rule 17.1 on a Petition for Writ of Certiorari. To then misstate those facts to this Supreme Court categorizes not only the merit of its petition but Petitioner's credibility as well.[4]

Ortho has had its day in court. After a procedurally perfect trial, extensive findings of fact and conclusions of law, an unsuccessful appeal of the same issues presented here and denial of motions for reconsideration and rehearing *en banc*, Petitioner steadfastly persists in clogging this Court's docket with argument of issues that do not warrant this Court's attention. Since there is ample evidence to support the trial court's conclusions, Ortho is not entitled to now remarshal those facts favorable to its argument in hopes that this Court will sit as another trier of fact.

The United States Supreme Court's review of issues on Writ of Certiorari is not a matter of right, but of judicial

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4. The failure of a petitioner to present with accuracy. . . the points requiring consideration will be a sufficient reason for denying his petition. Sup. Ct. R. 21.5.

discretion and will be granted only when there are special and important reasons. *Rice v. Sioux City Cemetery*, 349 U.S. 70,73 (1954), Sup. Ct. R. 17.1. The questions presented must involve principles, the settlement of which have importance to the public as distinguished from the parties. *Layne & Bowler Corp. v. Western Well Works, Inc.*, 261 U.S. 387,393 (1923). A loss on the merits is not a special and important reason.

II.

THE UNITED STATES COURT OF APPEALS, ELEVENTH CIRCUIT, NEITHER CREATED A NEW ORAL TESTIMONY STANDARD OR CONFLICT AMONG THE CIRCUITS.

A. The Eleventh Circuit's Review Of The Entire Record Complies With Fed. R. Civ. P. 52(a) and *Anderson v. City of Bessemer City*, 470 U.S. 564, 105 S. Ct. 1504 (1985).

Petitioner alleges the Eleventh Circuit, "narrowed the scope of its review to the *oral testimony* of Plaintiffs' experts. . ." without evaluating its plausibility in light of scientific evidence. OP-14. Petitioner made the same argument on appeal to the Eleventh Circuit alleging the District Court narrowed the scope of its decision to the oral testimony of Plaintiffs' experts without evaluating its plausibility in light of the scientific evidence. OAB-34-72.

Notwithstanding Petitioner's own argument at the Circuit level and the Circuit's express recognition of Fed. R. Civ. P. 52(a)[5] and *Anderson*,[6] (A-6), Petitioner would have this Court believe the Circuit Court never reviewed the rec-

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5. Fed. R. Civ. P. 52(a) provides in pertinent part, "Findings of fact, whether based on oral or documentary evidence, shall

(cont'd on next page)

ord in this case but relied solely on Plaintiffs' oral expert testimony thereby creating a new standard.

This oral testimony focus is belied by the opening portion of the Eleventh Circuit opinion wherein it was noted the panel reviewed "*the extensive factual record*" to affirm with respect to Ortho's liability. *Wells*, 788 F.2d at 742; A-2.

In next determining the accuracy of trial court findings of CAUSATION, the Eleventh Circuit stated, "*After reviewing the record* we reject Ortho's arguments and conclude that the district court's finding of causation is not clearly erroneous." *Id.* at 744; A-9 (emphasis supplied). The Eleventh Circuit further stated, "*We note.* . .[not the district court noted] that plaintiffs presented well qualified experts. . .[and] [P]laintiffs presented several epidemiological studies that indicated an association between spermicide use and deleterious effects on the fetus." *Id.*; A-9-10 (emphasis supplied).

In determining the accuracy of the trial court's findings on FAILURE TO WARN the Eleventh Circuit stated, "*We*

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not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses."

6. This Court in *Anderson* stated:

> "In applying the clearly erroneous standard to the findings of a district court sitting without a jury, appellate courts must *constantly* have in mind that their function is not to decide factual issues *de novo*." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 123, 89 S. Ct. 1562, 1576, 23 L.Ed.2d 129 (1969). If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently. Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous. *Id.* at 1511-12.

conclude that this finding is not clearly erroneous in light of the *evidence present in the record.*" *Id.* at 746; A-18 (emphasis supplied). The Eleventh Circuit, in recognizing several studies were available to Ortho prior to 1980, stated, "The district court found, *and we agree* that these studies were available to Ortho [prior to 1980]." *Id.* (emphasis supplied). The Eleventh Circuit necessarily reviewed the record in order to agree with the District Court findings.

Oral testimony became the focus of the Eleventh Circuit when addressing the District Court's reference to experts testifying about scientific studies and the credibility determinations necessarily made when that oral testimony was in direct conflict. After reviewing the methodology applied by the District Court the Circuit Court concluded, "We are satisfied that the district court's extensive credibility determinations are not clearly erroneous." *Id.* at 745 n. 8; A-14 at n. 8.

Excerpts of the Eleventh Circuit's opinion outlined above show the Panel did review the entire record including the District Court findings and conclusions prior to its unanimous decision of no clear error. Such a review is in direct conformity with Fed. R. Civ. P. 52(a) and decisions of this Court.[7]

B. Cases Cited By Petitioner Establish That No Conflict Exists Between The Circuits.

Petitioner has cited three cases for the proposition the methodology contained therein somehow conflicts with the

---

7. *Anderson, supra* and cases cited therein.

methodology applied by the Eleventh Circuit. Such is not true.

1. *Wisconsin v. Weinberger, 745 F.2d 412 (7th Cir. 1984)*; *OP-20-21*

Petitioner misstates this case in an attempt to suggest the *scientific studies* in evidence were dispositive on the issue of whether the Navy acted arbitrarily and capriciously in deciding not to perform an amended enviromental impact statement.

The Seventh Circuit fully recognized its duty was not to dissect the scientific evidence as Petitioner herein suggests, but to consider the evidence as a whole:

> Of course, it is not necessary for our purposes to consider in detail the merits of the scientific allegations and the alleged shortcomings of each piece of information and reach our own scientific decision about the project. *That is not our function.*
> *Id.* at 421 (emphasis supplied).

After considering the evidence as a whole the Seventh Circuit in *Weinberger* deemed it *insufficient* to carry the burden of proof to show the Navy acted arbitrarily and capriciously. The Eleventh Circuit in this case after considering the evidence as a whole deemed it *sufficient* to carry Plaintiffs' burden of proof.

2. *Moultrie v. Martin, 690 F.2d 1078 (4th Cir. 1982); OP-21.*

Petitioner's reliance on *Moultrie* is equally misplaced. *Moultrie* involved the appeal of a trial court's denial of a Writ of Habeas Corpus. The trial court had determined that statistical evidence presented to support a claim of dis-

crimination was insufficient and thus Petitioner failed to make out a prima facie case. The Appellate Court agreed and affirmed.

In the instant action however, the trial court determined that evidence (including statistical) presented to support proof of Causation and Failure To Warn was sufficient and Respondent *did* make out a prima facie case. The Appellate Court, as in *Moultrie*, agreed and affirmed.

3. *Lima v United States, 708 F.2d 502 (10th Cir. 1983)*; *OP-21.*

Lima is procedurally analogous to the instant action as it was a Rule 52 (a) bench trial on the issue of causation in a swine flu case. The trial court upon proper objection, ruled inadmissable the testimony of one of Plaintiff's expert witnesses and found Plaintiff did not carry his burden of proof. The Tenth Circuit, applying the clearly erroneous standard, affirmed the trial court findings.

In the present case there was no objection to Plaintiffs' expert testimony. The trial court concluded that Plaintiffs carried their burden of proof, and as in *Lima*, the Circuit Court applying the clearly erroneous standard, affirmed the trial court findings.

In summary, Petitioner has failed to show the Eleventh Circuit opinion conflicts with this Court's opinions or with the opinions of its sister circuits (*see also, Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 105 S. Ct. 545 (1984)). The Eleventh Circuit relied on *this Court's* controlling decisions and correctly applied the clearly erroneous standard to the facts before it. No conflict of decision exists in other circuits.

III.

PETITIONER'S COMPLAINTS ABOUT CREDIBILITY DETERMINATIONS AND DEFERENCE TO GOVERNMENTAL COMMITTEE FINDINGS ARE INAPPLICABLE TO THE FACTS OF THIS CASE.

Citing the Tort Policy Working Group's comments on Insurance Availability and Affordability (OP-23), Petitioner embraces two recommendations made by such group. The courts should first become more aggressive in determining the credibility of scientific and medical evidence and opinions; second, greater deference must be given to governmental agencies.

As to the courts being more aggressive in determining credibility, petitioner overlooks the fact this case is a prime example of such effort. As previously noted, the trial judge in addition to hearing courtroom testimony, routinely reviewed daily transcripts of much of the expert testimony and spent an entire weekend reviewing the scientific studies. As recognized by the Eleventh Circuit, the trial court made extensive credibility determinations applying appropriate methodology.[8]

Petitioner's argument for more aggressive credibility determination calls for all scientific cases being heard by a trial judge to avoid jury sympathy and reliance on a particular expert because the jury likes the witness. A Federal

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8. In assessing credibility the court looked at each expert's background, training, experience, and familiarity with the circumstances of this particular case. The court examined each expert's testimony in terms of its rationality and internal consistency in relation to all the evidence presented. The court also looked at each expert's demeanor and tone and searched for motives, biases, and interests that might have influenced opinion. *Wells*, 788 F.2d at 745 n.8; A-14 at n. 8.

District Court Judge sitting without a jury having tried this case, Petitioner's complaint appears to be the adverse result of the very process it embraces.

The second recommendation of the Tort Policy Working Group urged by Petitioner is greater deference to governmental committee recommendations. (OP-24 n.2).

Petitioner has selected the *wrong case* to espouse the theory of deference to governmental agencies. The two reports introduced by Petitioner upon the trial of this case and considered by the District Court and Eleventh Circuit, when subjected to *discovery* and *cross examination* showed gross incompetence and corporate influence by Ortho.

As to the first agency advisory panel relied on by Petitioner (The O.T.C. Advisory Committee) (OP-5):

> Discovery and Cross Examination were able to establish *at least* the following:
>
> Dr. Armond Welsh, a committee member, testified for Ortho as to information gathered by the committee prior to its 1980 recommendation. The report was *tainted with incompetence* when Dr. Welsh testified on cross examination, that during the 1970's there was a *rumor* of a report at NIH [Oechsli Study (1976)] which linked spermicides with birth defects. Though it was his job to do so, Dr. Welsh never got the report and never confirmed the *rumor*, yet the committee proceeded to denote the product "safe and effective". T 1103.

As to the second agency advisory panel relied on by Petitioner (FMHDAC) (OP-5):

This advisory subcommittee of the FDA, met on December 15, 1983 and discussed whether or not they should

recommend the addition of a pregnancy warning to spermicides.

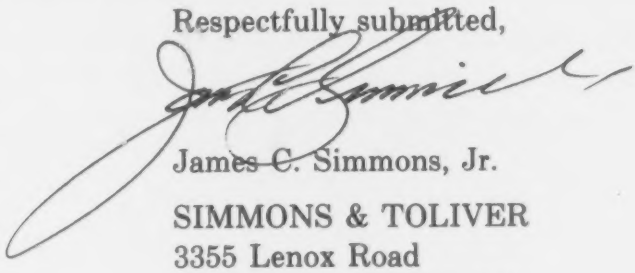
> Discovery and Cross Examination were able to establish *at least* the following:
>
> The committee consisted of seven members who heard testimony from sixteen individuals, at least six of whom were either employed by, or paid travel expenses and consulting fees by Ortho Pharmaceutical Corporation. T-1540. Dr. Brent, Ortho's key expert at trial, was one of the seven voting committee members though he did not *recuse* himself or *disclose* to his fellow judges his prior contact with Ortho and his involvement with this lawsuit for six (6) months prior to the hearing. T-1678.

Petitioner urges blind acceptance of governmental agency (Advisory Subcommittee) conclusions as controlling in a state tort action. The incompetence of the O.T.C. Advisory Committee's literature search and the influence Ortho had on both the FMHDAC Panel of Judges and those presenting testimony were important items considered by the District Court in determining how much weight to give their conclusions. Deference to these committee findings could well have shielded their failings from discovery. This very case is an example of how the adversary process with full right of cross examination adds assurance the Judgment will reflect the *truth and right of the case.*

CONCLUSION

For the reasons set forth above, Ortho's Petition for a Writ of Certiorari should be denied.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that I have this day served the foregoing RESPONDENTS' BRIEF IN OPPOSITION upon Petitioner by depositing four copies of same in the United States mail, first class, postage prepaid to:

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